PRODUCT STERILIZATION REPORT

Title:	Medtronic CRHF Therapy Delivery System Product Compliance to ISO 10993-7:2008/AC:2009		
Product:	CRHF Therapy Delivery System Leads, Accessories and Adaptors	Doc. No.:	10173449DOC
Process:	30-minute EO exposure process	Date:	04 December 2014
Topic:	Product Residual and Tolerable Contact Limit Compliance	Pages:	92
Key Words	Leads, Accessories, Adaptors, Residual, TCL, EO, ECH		

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1.0 PURPOSE:

The purpose of this report is to determine if all Medtronic CRHF Therapy Delivery System (TDS) internally manufactured leads, accessory and adaptor products comply with residual requirements stated in ISO 10993-7: 2008/AC:2009 (ref. section 4.0) after being sterilized in the 3M™ 100% ethylene oxide (EO) 5XLe tabletop sterilizer systems.

2.0 SCOPE:

The activities described in this report incorporated the following requirements:

- Determined and tested worst case lead, accessory and adaptor models that represent Medtronic CRHF TDS internally manufactured product families to ensure compliance with residual requirements stated in ISO 10993-7:2008/AC:2009 (ref. section 4.0) utilizing single and/or multiple sterilization cycles using a 30-minute EO exposure process [the Rice Creek 091033-050 sterilization process (ref. section 4.0) or equivalent manufacturing facility's sterilization process parameters] as described in section 8.0 of BSH111461PC (ref. section 4.0). Test samples were exposed to routine EO exposure parameters and worst case aeration and parameters where applicable.
- The manufacture, assembly and packaging of the selected lead and accessory models described in Section 3.0 were performed at the Medtronic Puerto Rico Operations Company (MPROC)-Villalba (Villalba, Puerto Rico) and Rice Creek (Fridley, MN.) manufacturing facilities.
- As Medtronic sterilizers and aerators are equivalent (per CSS-0901-0001-0019 and CRM-0902-0001), all sterilization and aeration activities that were performed as part of this report were performed at the CRHF Rice Creek facility utilizing the 091033-050 manufacturing process and represent equivalent 30-minute 100% EO sterilization processes used throughout Medtronic. **Note**: Each Medtronic facility that performs internal 30-minute 100% EO sterilization may use different "letter or name designations" for applicable loading configurations than what is utilized in the 091033-050 manufacturing process; however, load densities, quantities of product per load and loading configurations are the same.

3.0 BACKGROUND & PRODUCT DESCRIPTION:

In 2008, a new revision of ISO 10993-7 was approved and released and conflicting national standards shall be withdrawn at the latest by October 2011.

The acceptance criteria for EO and ethylene chlorohydrin (ECH) residual limits were updated from what was listed in the previous issue of ISO 10993-7:1995 (see Tables 1 and 2). In addition, a new requirement, called the Tolerable Contact Limit (TCL), was implemented to determine possible EO and ECH irritation within a patient and replaces the 250 ppm requirement

of AAMI TIR 19 (ref. section 4.0). All legacy internally EO sterilized CRHF TDS lead, accessory and adaptor legacy products were originally qualified to the 1995 version of ISO 10993-7. Therefore, all previously qualified (to 10993-7:1995 acceptance criteria) Medtronic CRHF TDS internally EO sterilized lead, accessory and adaptor products require assessment to ensure they meet the new residual and TCL requirements listed in ISO 10993-7:2008/AC:2009.

Note: For informational purposes, ethylene glycol (EG) is monitored, but is not reported. Recent risk assessment studies have demonstrated that when EO residues are controlled as required, it is unlikely that biologically significant residues of EG would be present.

In order to assess the Medtronic CRHF TDS internally manufactured and EO sterilized legacy lead, accessory and adaptor products. These products were divided into four groups: pacing leads (Group 1), high voltage leads (Group 2), accessories/adaptors (Group 3) and drug delivery catheters (Group 4) (Sections 3.1, 3.2, 3.3 and 3.4). Worst case models from within each of these groups were then chosen as representative models for each product group by utilizing some or all of the following criteria (varies per group): aeration, primary body material composition, body diameters, length of lead, polarity, concentration of components and sterile packaging. These products are listed in Tables 4, 5, 6, 7, 8, 11, 12, 13, 14, 17, 18, 19 and 20. See "Criteria Breakdown" and "Group Criteria Breakdown" below for a complete rationale.

CRITERIA BREAKDOWN:

Note: Ranked in order of residual retaining criticality.

Aeration– Primary Testing Criteria Determination

Specified models were either divided into separate aeration categories or were used to decide what product required more aeration to remove appropriate levels of EO/ECH residue. See group criteria breakdown below.

Material Composition – Secondary Testing Criteria Determination

Historically, product materials such as polyurethane and silicone have shown to retain EO/ECH residue more than other materials such as stainless steel or titanium. Therefore, lead models and components primarily composed of silicone and or polyurethane were chosen over models made of stainless steel or titanium.

Body Diameter– Tertiary Testing Criteria Determination

The larger a body diameter of a lead or adaptor model the more material/insulation there is to retain higher levels of EO/ECH residue. Hence, models with larger body diameters were chosen over smaller body diameters.

Length of Lead - Quaternary Testing Criteria Determination

The longer the length of a lead the probability of obtaining more EO/ECH residual is higher. Lead models with the longest length were chosen over shorter lengths. However, such criteria as body diameter or polarity may outweigh the length of a lead model (depending on criteria listed) for worst case criteria. See deviation section 10.16.

Polarity – Quinary Testing Criteria Determination

Product models that exhibit more polarity contain a larger surface area which results in a higher concentration of EO/ECH residue. Thus, models with the most polarity were chosen.

Component Concentration – Senary Testing Criteria Determination

Models that contain the greatest quantity of components exhibit the possibility of containing higher levels of EO/ECH residue (depending on primary material composition). Therefore, specified product models were chosen that contained more components.

Sterile Packaging – Septenary Testing Criteria Determination

Chosen worst case models were assessed based on each models' qualified sterile packaging configurations.

GROUP CATEGORY BREAKDOWN:

Pacing and High Voltage Leads – Groups 1 and 2

The Medtronic CRHF TDS internally sterilized pacing and high voltage lead models were divided into four separate aeration categories within the two respective families based on each model's aeration specification: 2-16 hours, 4-16 hours, 8-16 hours and 12-16 hours. Within each of the four separate aeration categories worst case models were chosen to represent each of the aeration categories by comparing the primary body material composition (silicone or polyurethane), body diameters, lead lengths, polarity and sterile packaging. One silicone and/or polyurethane and/or

silicone/polyurethane lead with the largest body diameter and greatest polarity was chosen within each aeration category (ref. sections 3.1 and 3.2). If a particular model contained two different sterile packaging configurations, then both were assessed.

Models that have been phased out (no longer manufactured or sold) were not assessed and are listed in Tables 9 and 15. Models in development that have not yet been qualified for EO sterilization are listed in Tables 10 and 16.

Accessories and Adaptors – Group 3

The Medtronic CRHF TDS internally sterilized accessory and adaptor models were divided into three separate categories: implantable adaptors and extenders, small accessory implants and non-implantable accessories. Within each of the three separate categories, worst case models were chosen to represent each of the categories.

A worst case model for implantable adaptors and extenders was chosen by comparing the primary body material composition (silicone or polyurethane), body diameters, polarity, aeration, product components and sterile packaging. Silicone adaptors and extenders (no polyurethane composition is contained within the adaptors or extenders) with the largest body diameter or greatest polarity and the greatest concentration of components were chosen (ref. section 3.3). All adaptors and extenders assessed contained equal amounts of aeration (4-16 hours). If a particular model contained two different sterile packaging configurations, then both were assessed.

A worst case model for small implantable accessories was chosen by comparing the primary body material composition, body diameters, aeration, product components and sterile packaging. Silicone adaptors and extenders (no polyurethane composition is contained within the adaptors or extenders) with the largest body diameter and the greatest concentration of components were chosen (ref. section 3.3). If a particular model contained two different sterile packaging configurations, then both were assessed.

A worst case model for non-implantable accessories was chosen by comparing the primary body material composition, aeration, product components and sterile packaging. Non-implantable product with the most challenging material (such as silicone or polyurethane) composition and greatest concentration of components was chosen (ref. section 3.3). However, two stylet models with the largest body diameters and greatest concentration of components were chosen regardless of being primarily comprised of stainless steel to represent the Medtronic CRHF TDS stylet models. If a particular model contained two different sterile packaging configurations, then both were assessed.

Accessory and adaptor models that have been phased out (no longer manufactured or sold) were not assessed and are listed in Table 21. OEM models are listed in Table 22 and will not be assessed since they are outside the scope of this report. Models in development that have not yet been qualified for EO sterilization are listed in Table 23 and will be tested as per ISO 10993-7: 2008/AC:2009 (ref. section 4.0) upon appropriate product development phase.

Drug Delivery Catheter – Group 4

The Medtronic CRHF 10642/8201 drug delivery catheter was the only model within this group that was assessed. See Table 24 for product description.

3.1 Acceptance Criteria

Tables 1 and 2 below exhibit the EO and ECH residual acceptance criteria differences between the 1995 and 2008/AC:2009 versions of ISO 10993-7. The TCL acceptance criteria are listed in Table 3.

Table 1: ISO 10993-7:1995 Acceptance Criteria

Acceptance Criteria	Exposure Type: Permanent/Limited/Both	EO	ECH
Dose for first 24 hours not to exceed	Both	20 mg	12 mg
Dose for first 30 days not to exceed	Permanent	60 mg	60 mg
Lifetime dose not to exceed	Permanent	2.5 g	50 g
Average daily dose not to exceed	Permanent	0.1 mg/day	2 mg/day

Table 2: ISO 10993-7:2008/AC:2009 Acceptance Criteria

Acceptance Criteria	Exposure Type: Permanent/Limited/Both	EO	ECH
Dose for first 24 hours not to exceed	Both	4 mg	9 mg
Dose for first 30 days not to exceed	Permanent	60 mg	60 mg
Lifetime dose not to exceed	Permanent	2.5 g (2,500 mg)	10 g (10,000 mg)
Average daily dose not to exceed	Permanent	0.1 mg/day	0.4 mg/day

Table 3: TCL Acceptance Criteria

Residue	Acceptance Criteria
EO	Not to exceed 10 µg/cm^2 or shall exhibit 1.0 or less for irritation as specified in ISO 10993-10 (ref. section 4.0)
ECH	Not to exceed 5 mg/cm^2 or shall exhibit 1.0 or less for irritation as specified in ISO 10993-10 (ref. section 4.0)

3.2 CRHF TDS Pacing Lead Models and Criteria - GROUP 1

Table 4: - Pacing Lead Models (Composed of Polyurethane/Silicone and Silicone) Based on a Minimum of 2 Hours Aeration at 1X Sterilization

Model	Longest Length (cm)	Group Design	Primary Material Composition	Body Diameter of Tubing	Polarity	Package Type
5054	65	Lead	Silicone	2.0 mm	Bipolar	Standard Lead Tray
5554 / Vitatron IHP09JB	53	Lead	Silicone	2.0 mm	Bipolar	Standard Lead Tray/DELP
5033	65	Lead	Silicone	2.6 mm	Unipolar	Standard Lead Tray/DELP
5594	100	Lead	Outer Tubing: Silicone w/Siloxane Inner Tubing: Silicone	2.0 mm	Bipolar	DELP
5092	65	Lead	Silicone	2.0 mm	Bipolar	Standard Lead Tray/DELP
4092	85	Lead	Outer Tubing: Polyurethane Inner Tubing: Silicone	1.8 mm	Bipolar	Standard Lead Tray
5592	53	Lead	Silicone	2.0 mm	Bipolar	Standard Lead Tray/DELP
4592 / Vitatron IMK49JB	53	Lead	Outer Tubing: Polyurethane Inner Tubing: Silicone	1.8 mm	Bipolar	DELP
4074 / NPX102 / Vitatron ICM09B	85	Lead	Outer Tubing: Polyurethane Inner Tubing: Silicone	1.8 mm	Bipolar	DELP
4574 /	53	Lead	Outer Tubing:	1.8 mm	Bipolar	DELP

Model	Longest Length (cm)	Group Design	Primary Material Composition	Body Diameter of Tubing	Polarity	Package Type
NPX103 / Vitatron ICM09JB			Polyurethane Inner Tubing: Silicone			
4084	58	Lead	Outer Tubing: Polyurethane Inner Tubing: Silicone	1.8 mm	Bipolar	DELP
4084MRI	58	Lead	Outer Tubing: Polyurethane Inner Tubing: Silicone	1.8 mm	Bipolar	DELP
4584MRI	53	Lead	Outer Tubing: Polyurethane Inner Tubing: Silicone	1.8 mm	Bipolar	DELP
5076 / NPX101 / Vitatron ICF09/ICF09B	110	Lead	Silicone w/Siloxane	2.0 mm	Bipolar	DELP
4076 / Vitatron ICQ09B	***110****	***Lead***	***Polyurethane / Silicone with Siloxane***	***1.9 mm***	***Bipolar***	***DELP***
5086MRI	58	Lead	Silicone w/Siloxane	2.0 mm	Bipolar	DELP
5568	***53***	***Lead***	***Silicone***	***2.4 mm***	***Bipolar***	***Standard Lead Tray/DELP***
5072	65	Lead	Silicone	2.4 mm	Bipolar	Standard Lead Tray/DELP
5071	53	Lead	Silicone	2.2 mm	Unipolar	Myocardial
Vitatron IMK49B (Medtronic model 4092)	85	Lead	Outer Tubing: Polyurethane Inner Tubing: Silicone	1.8 mm	Bipolar	Standard Lead Tray
Vitatron ICL08	85	Lead	Silicone	1.8 mm	Bipolar	Standard Lead Tray
ICL08B	65	Lead	Silicone	2.2 mm	Bipolar	Standard Lead Tray/DELP
ICL08JB	53	Lead	Silicone	2.2 mm	Bipolar	Standard Lead Tray/DELP
4396	88	Lead	Polyurethane/silicone	1.3 mm	Bipolar	DELP
4196	103	Lead	Outer Tubing: Polyurethane Inner Tubing: Polyimide	1.3 mm	Bipolar	DELP

*Representative worst case models for pacing leads (composed of polyurethane/silicone) at a minimum of 2 hours aeration for 1X Sterilization and multiple cycles. The model 4076 is compliant to ISO 10993-7:2008/AC:2009 for the following lengths: 25, 35, 45, 52 and 58 cm. The 65, 85 and 110 cm length 4076 leads were tested for compliance by using the worst-case length (110cm). The **4076-110** lead model **represents all of the silicone and polyurethane/silicone models** in Table 4 for the following reasons:

1. The 4076 model contains polyurethane. Polyurethane is historically the worst case absorbing material compared to silicone.
2. Longest length of 110 cm. The longer length could result in higher EO/ECH residual retention.
3. Bipolar. Higher polarity results in a higher surface area.

Model was tested for residual verification for leads composed of silicone (5568: Tables 48 – 57). The 4076-110 lead model **represents all of the silicone and polyurethane/silicone models in Table 4 based on criteria stated above.
***See deviation section 10.10.

Table 5: - Pacing Lead Models (Composed of Polyurethane) Based on a Minimum of 2 Hours Aeration at 1X Sterilization

Model	Longest Length (cm)	Group Design	Primary Material Composition	Body Diameter of Tubing	Polarity	Package Type
4073 / Vitatron ICM09	***65***	***Lead***	***Polyurethane***	***1.2 mm***	***Unipolar***	***DELP***

*Representative worst case model for pacing leads (composed of polyurethane) at a minimum of 2 hours aeration for 1X Sterilization. Reference results section 9.0 for documented results (4073: Tables 78 – 82)

Table 6: Pacing Lead Models (Composed of Polyurethane/Silicone and Silicone) Based on a Minimum of 4 Hours Aeration at 1X Sterilization

Model	Longest Length (cm)	Group Design	Primary Material Composition	Body Diameter of Tubing	Polarity	Package Type
3830	110	Lead	Outer Tubing: Polyurethane Inner Tubing: Silicone	1.4 mm	Bipolar	Standard Lead Tray
5038 / Vitatron IMW18Q, IMW17Q, IMW16Q, IMW15Q, IMW14Q	***65***	***Lead***	***Silicone***	***2.7 mm***	***Quadripolar***	***Standard Lead Tray / DELP***
5038S	65	Lead	Silicone	2.7 mm	Quadripolar	Standard Lead Tray / DELP
5038L	65	Lead	Silicone	2.7 mm	Quadripolar	Standard Lead Tray / DELP
4968	60	Lead	Silicone	2.7 mm	Bipolar	Myocardial
4965	50	Lead	Silicone	1.5 mm	Unipolar	Myocardial
4194	***103***	***Lead***	***Outer Tubing: Polyurethane Inner Tubing: Silicone***	***2.0 mm***	***Bipolar***	***DELP***
IHP09	65	Lead	Silicone	1.4 mm	Unipolar	DELP
IHP09B	65	Lead	Silicone	2.0 mm	Bipolar	DELP

*Representative worst case models for pacing leads (composed of polyurethane/silicone) at a minimum of 4 hours aeration for 1X Sterilization and multiple cycles. Reference results section 9.0 for documented results (4194: Tables 73 - 77). The **4194-103** lead model **represents all of the silicone and polyurethane/silicone models** in Table 6 for the following reasons:

1. Model contains polyurethane. Polyurethane is historically the worst case absorbing material compared to silicone.
2. Longest length of 103 cm. The longer length could result in higher EO/ECH residual retention.

** Representative worst case models for pacing leads (composed of silicone) at a minimum of 4 hours aeration for 1X Sterilization. Reference results section 9.0 for documented results (5038: Tables 58 – 66). Primary reasons why 5038 was chosen for the silicone models in Table 6:

1. Body diameter of 2.7 mm. The thicker body diameter could result in higher EO/ECH residual retention.
2. Polarity of quadripolar. Higher polarity results in a higher surface area.

Table 7: Pacing Lead Models (Composed of Polyurethane) Based on a Minimum of 4 Hours Aeration at 1X Sterilization

Model	Longest Length (cm)	Group Design	Primary Material Composition	Body Diameter of Tubing	Polarity	Package Type
4193	***103***	***Lead***	***Polyurethane***	***1.4 mm***	***Unipolar***	***DELP***
4189	85	Lead	Polyurethane	1.4 mm	Unipolar	DELP
4191	85	Lead	Polyurethane	1.4 mm	Unipolar	DELP
5803A	31.75	Lead	Polyurethane	1.4 mm	Unipolar	DELP

*Representative worst case model for pacing leads (composed of polyurethane) at a minimum of 4 hours aeration for 1X Sterilization and multiple cycles. Reference results section 9.0 for documented results (4193: Tables 68 – 72). The **4193-103 represents all of the polyurethane leads listed in Table 7**. The reason why the 4193-103 was chosen as the representative model over the other models is as follows:

1. Longest length of 103 cm. Other models contain the same material, body diameter, polarity and package type. The longer length could result in higher EO/ECH residual retention.

Table 8: Pacing Lead Models (Composed of Polyurethane) Based on a Minimum of 8 Hours Aeration at 1X Sterilization

Model	Longest Length	Group Design	Primary Material Composition	Body Diameter of Tubing	Polarity	Package Type
4195	***103****	***Lead***	***Polyurethane***	***1.7 mm***	***Unipolar***	***DELP***
4296	***88***	***Lead***	***Polyurethane***	***1.7 mm***	***Bipolar***	***DELP***

*Representative worst case model for pacing leads (composed of polyurethane) at a minimum of 8 hours aeration for 1X Sterilization and multiple cycles. The **4195-103** lead model **represents all of the models listed in Table 8 as the worst-case model.**

Rationale why the 4195-103 lead model was selected in Table 8:

1. Longest length of 103 cm. The 4296 model is 88 cm. The longer length could result in higher EO/ECH residual retention.

** The 4296 lead model was chosen as the worst case model in protocol BSH111461PC. However, upon the addition of longest lengths as a worse-case criterion in report BSH111461FR for each lead model it was discovered that the 4195-103 was the worst-case lead model. The 4296 has been qualified and meets 10993-7:2008/AC:2009 acceptance criteria. Therefore, testing was not required. Reference results section 9.0 for documented results (Tables 88 – 92). Model was originally chosen as a worst case model for the following reason:

1. Bipolar. Other models are unipolar and contain the same material, body diameter and package type as the 4296. However, the longest length for the 4296 (88 cm) is shorter than the longest length for the 4195 (103 cm). Therefore, it was decided to claim that the 4195-103 is worst case. The residual information for the 4296's can be used for informational purposes.

***See deviation section 10.11.

Table 9: Phased-Out Pacing Lead Models Not Assessed

Model Numbers			
2957	5068	4951M	4523
4033	4068	5023	4081
4533	4557M	5524M	2188
5024M	4328B	5023M	4023
IMD19	IMD49	IME49	IME49B
IME49JB	IMG49	IML49JB	IML49B
IMX49JB	IMX49B	IMX49	6230
6229	6227	4504M	2187
2956	2893	2775	2892
4328	4755	ICF09	IRP13

Table 10: CRHF Pacing Lead Models in Development and Not Qualified for EO Sterilization

Model Numbers			
*4080	*4580	*4298	*4398

*Models will be qualified for EO sterilization according to 10993-7:2008/AC:2009 once qualification testing begins as per each product sterilization protocol.

3.3 CRHF TDS High Voltage Lead Models and Criteria – Group 2

Table 11: High Voltage Lead Models Based on a Minimum of 2 Hours Aeration at 1X Sterilization

Model	Longest Length (cm)	Group Design	Primary Material Composition	Body Diameter of Tubing	Polarity	Package Type
***7927**	***100 (see note)**	***Lead**	***Silicone**	***2.2 mm**	***Bipolar**	***DELP**

*Representative worst case model for high voltage leads at a minimum of 2 hours aeration for 1X Sterilization (and multiple cycles), which has been qualified at the 65 cm length and meets 10993-7:2008/AC:2009 acceptance criteria. Therefore, testing is not required (ref. section 4.0). Reference results section 9.0 for documented results (Tables 24 – 28).

Note: The 100 cm length is still in development stage and will be tested to 10993-7:2008 criteria once qualified.

Table 12: High Voltage Lead Models Based on a Minimum of 4 Hours Aeration at 1X Sterilization

Model	Longest Length (cm)	Group Design	Primary Material Composition	Body Diameter of Tubing	Polarity	4 Package Type
***6721 (S,M,L)**	***L**	***Patch Lead**	***Silicone**	***2.5 mm**	***Unipolar**	***Pouch**
6937	110	Lead	Silicone	1.8 mm	Unipolar	Standard Lead Tray
***6996SQ**	***85**	***Lead**	***Silicone**	***2.5 mm**	***Unipolar**	***Standard Lead Tray**
6933	110	Lead	Silicone	1.8 mm	Unipolar	Standard Lead Tray

*Representative worst case model for high voltage leads at a minimum of 4 hours aeration for 1X Sterilization and multiple cycles. Reference results section 9.0 for documented results (6996SQ: Tables 43 - 47). The reason why the **6996SQ-85** was chosen as the **representative model** over the 6937 and 6933 models is as follows:

1. Body diameter of 2.5 mm for the 6996SQ vs. 1.8 mm for the 6933 and 6937 models. The additional body diameter results in more material to absorb EO/ECH. It is more difficult to remove EO through the aeration process from a thicker body diameter than from a less thick body diameter that's longer.

**** Representative worst case model for high voltage patch lead at a minimum of 4 hours aeration for 1X Sterilization. Reference results section 9.0 for documented results (6721L: Tables 34 – 37). Reason why the 6721L was chosen:

1. No EO/ECH residual data existed for the large (L) patch model.
2. The large (L) patch model contains the most surface area. The larger the surface area the more potential for retaining higher levels of EO/ECH.
3. No other patch models to compare EO/ECH data against.

Table 13: High Voltage Lead Models Based on a Minimum of 8 Hours Aeration at 1X Sterilization

Model	Longest Length (cm)	Group Design	Primary Material Composition	Body Diameter of Tubing	Polarity	Package Type
6944	100	Lead	Silicone	2.7 mm	Quadripolar	Standard Lead Tray
6935 / NDX101	100	Lead	Silicone	2.8 mm	Tripolar	Standard Lead Tray

6947M / NDX402[1]	97	Lead	Silicone	2.4 mm	Quadripolar	DELP
6947/NDX102[2]	***100 for 6947 and 75 for NDX102***	***Lead***	***Silicone***	***2.8 mm***	***Quadripolar***	***Standard Lead Tray***
6935M[3]	97	Lead	Silicone	2.8 mm	Tripolar	DELP
6944A[4]	100	Lead	Silicone	2.7 mm	Quadripolar	DELP
6946M[5]	97	Lead	Silicone	2.4 mm	Quadripolar	DELP

[1] See sterilization report BL0027436 for EO/ECH testing results. In previous versions of this report this model was listed as being sterile packaged in standard lead tray and represented by the 6947-100 model. However, since this model is sterile packaged in DELP packaging it was analyzed by itself for EO/ECH residuals.

[2] Representative worst case model for high voltage leads at a minimum of 8 hours aeration for 1X Sterilization and multiple cycles (not including models 6935M, 6946M and 6944A; see superscript notes 3-5 below). The 100 cm length 6947 leads are being tested for compliance by using the worst-case length (100cm). Reference results section 9.0 for documented results (Tables 38 – 42).
Reason why the **6947-100** was chosen as the **representative model** over the other models is as follows:

1. Body diameter of 2.8 mm. The additional body diameter results in more material to absorb EO/ECH. It is more difficult to remove EO through the aeration process from a thicker body diameter than from a less thick body diameter that's longer.
2. Quadripolar. Higher polarity results in a higher surface area.
3. Lead length of 100 cm. The longer length could result in higher EO/ECH residual retention

[3] Model was not qualified for sterilization in previous versions of this report and was listed in Table 16 as a lead model in development. The model has since been qualified for sterilization (See report BL0024585).
[4] Model was not qualified for sterilization in previous versions of this report and was listed in Table 16 as a lead model in development. The model has since been qualified for sterilization (See report BL0023825)
[5] Model was not qualified for sterilization in previous versions of this report and was listed in Table 16 as a lead model in development. The model has since been qualified for sterilization (See report BL0025829)

Table 14: High Voltage Lead Models Based on a Minimum of 12 Hours Aeration at 1X Sterilization

Model	Longest Length (cm)	Group Design	Primary Material Composition	Body Diameter of Tubing	Polarity	Package Type
****6937A***	***100***	***Lead***	***Outer Tubing: Polyurethane Inner Tubing: Silicone***	***2.5 mm***	***Unipolar***	***Standard Lead Tray***

*Representative model for high voltage leads at a minimum of 12 hours aeration for 1X Sterilization and multiple cycles. Reference results section 9.0 for testing results (Tables 29 – 33).

Table 15: Phased-Out High Voltage Lead Models Not Assessed

Model Numbers			
6948	6931	6943	6930
6949	6932	6945	6942
6897L	6897M	6897S	6930M
6931M	6948M	6949M	6996
6940	6963	6996S	6996ST

Table 16: CRHF High Voltage Lead Models in Development and Not Qualified for EO Sterilization

Model Numbers	
7926M[1]	7916M[1]
7927M[1]	7917M[1]

[1] Models will be qualified for EO sterilization according to 10993-7:2008/AC:2009 once qualification testing begins as per each product sterilization protocol.

3.4 CRHF TDS Accessory and Adaptor Models and Criteria – Group 3

Table 17: Implantable Adaptors (Kits) and Extender Models Based at 1X Sterilization

Model	Longest Length (cm)	Group Design	Primary Material Composition	Body Diameter	Polarity	Components	1X Aeration Time	Package Type
5866-9M	16.5	Adaptor	Silicone	4 mm	Unipolar	Adaptor, Adhesive, 2 wrench and Mach screw sets and 1 cap-tube	4 hours minimum	Accessory Tray
***5866-22	8.1	Adaptor	Silicone	3.2 mm	Bipolar	Adaptor, 4 wrench and Mach screw sets	4 hours minimum	Accessory Tray
2872	11.2	Adaptor	Silicone	4 mm	Unipolar	Adaptor, Adhesive, 4 wrench and Mach screw sets and 1 cap-tube	4 hours minimum	Accessory Tray
**5866-24M	16.5	Adaptor	Silicone	5 mm	Unipolar	Adaptor, Adhesive, 4 wrench and Mach screw sets and 1 cap-tube	4 hours minimum	Accessory Tray
5866-37M	16.5	Adaptor	Silicone	4 mm	Unipolar	Adaptor, Adhesive, 2 wrench and Mach screw sets and 1 cap-tube	4 hours minimum	Accessory Tray
5866-38M	15.2	Adaptor	Silicone	4 mm	Unipolar	Adaptor, Adhesive, 4 wrench and Mach screw sets and 1 cap-tube	4 hours minimum	Accessory Tray
5866-40M	14.1	Adaptor	Silicone	3.2 mm	Unipolar	Adhesive, 4 wrench and Mach screw sets and 1 cap-tube	4 hours minimum	Accessory Tray
5866-21	14.1	Adaptor	Silicone	5 mm	Unipolar	Adaptor, Adhesive, 4 wrench and Mach screw sets and 1 cap-tube	4 hours minimum	Accessory Tray
5866-36	15.7	Adaptor	Silicone	5 mm	Unipolar	Adaptor, 4 wrench and Mach screw sets	4 hours minimum	Accessory Tray

Model	Longest Length (cm)	Group Design	Primary Material Composition	Body Diameter	Polarity	Components	1X Aeration Time	Package Type
5866-23	2.6	Adaptor	Silicone	3.2 mm	Unipolar	Sleeve	4 hours minimum	Accessory Tray
6056M	****	Adaptor-Kit	Silicone	****	Unipolar	Adaptor, Stylet Guide, Pinch on Tool, Rotational Tool, ACI	4 hours minimum	Accessory Tray
6981M	37	Extender	Silicone	3.2 mm	Unipolar	Extender, Adhesive, 2 wrench and Mach screw sets and 1 cap-tube	4 hours minimum	Standard Lead Tray
6984M	37	Extender	Silicone	3.2 mm	Unipolar	Extender, Adhesive, 4 wrench and Mach screw sets and 1 cap-tube	4 hours minimum	Standard Lead Tray
6986M	***39***	***Extender***	***Silicone***	***3.2 mm***	***Unipolar***	***Extender, Adhesive, 4 wrench and Mach screw sets and 1 cap-tube***	***4 hours minimum***	***Standard Lead Tray***
6985M	50	Extender	Silicone	3.2 mm	Unipolar	Extender	4 hours minimum	Accessory Tray
6707	35	Adaptor / Extender	Silicone	1.8 mm	Unipolar	Adaptor, 2 wrench and Mach screw sets and 1 cap-tube	4 hours minimum	Accessory Tray
6726	35	Adaptor / Extender	Silicone	3.4 mm	Unipolar	Adaptor, Pin Plug, Hex Wrench	4 hours minimum	Accessory Tray

*Representative worst case models for Extenders and Adapters at a minimum of 4 hours aeration for 1X Sterilization and multiple cycles. Reference results section 9.0 for testing results (Tables 102 – 106). The **6986M** model **<u>represents</u> all of the Extenders and Adapters** in Table 17 for the following reasons:

1. Models 6985M, 6707, 6726 and 6981M contain less components than the 6986M. Therefore, less EO/ECH absorption. The 6984M contains the same material, body diameter, polarity, surface areas (32.95 cm^2) and components as the 6986M. However, the 6986M is 2 cm longer. Therefore, it was decided to choose the 6986M.
2. Even though the 6985M is longer in length than the 6986M it does not contain a larger surface area. The 6986M contains a surface area of 32.95 cm^2 and the 6985M contains a surface area of 25.54 cm^2. The difference of 7.41 cm^2 in surface area will result in an increase of EO/ECH residual retention.
3. The 6986M extender is 23 cm longer than all other adapters listed in Table 17. This additional length can account for additional EO/ECH retention.

**Representative worst case models for Adaptors at a minimum of 4 hours aeration for 1X Sterilization, which has been qualified and meets 10993-7:2008/AC:2009 acceptance criteria. Therefore, testing was not required. Reference results section 9.0 for documented results (5866-24M: 122 – 126). The 5866-24M was initially thought to be worse case however, when compared to the 6986M (see above) it was found that the 6986M could represent all models in Table 17. The 5866-24M was initially chosen for the following reasons:

1. Body diameter of 5 mm.
2. Most components contained within packaging compared to other adaptor sets, except for models 5866-21, 5866-38M and 5866-37M, which all have the same concentrations of components, material composition, and polarity as the 5866-24 model. However, the 5866-24M contains a larger body diameter. The additional body diameter results in more material to absorb EO/ECH.

*** Representative worst case model for Adaptors at a minimum of 4 hours aeration for 1X Sterilization, which has been qualified and meets 10993-7:2008/AC:2009 acceptance criteria. Therefore, testing was not required. Reference results section 9.0 for documented results (5866-22: Tables 128 -131). The 5866-22 was chosen based on the following reasons:

1. Bipolar. The adaptor has a smaller body diameter but contains an increased surface area. The model was chosen to ensure that being bipolar verses the unipolar adaptors would have no effect on EO/ECH retention.

****No adaptor in this kit, just components.

Table 18: CRHF Small Accessory Implants Based at 1X Sterilization

Model	Group Design	Primary Material Composition	Components	1X Aeration Time	Package Type
5867-3M	End Caps	Silicone	4 - End Caps	4 hours minimum	Accessory Tray
6701	End Caps	Silicone	1 - End Cap	4 hours minimum	Accessory Tray
5866-45	Connector Sleeves	Silicone	1 - Connector Sleeve	48 hours minimum	Accessory Tray
***5866-46**	***Connector Sleeves**	***Silicone**	***4 - Connector Sleeves**	***48 hours minimum**	***Accessory Tray**
****6717**	***Pin Plug**	***Silicone**	***2- Pin Plugs**	***4 hours minimum**	***Accessory Tray**
6726	Pin Plug	Silicone	1 - Pin Plug	4 hours minimum	Accessory Tray
6725	Pin Plug	Silicone	1 - Pin Plug	4 hours minimum	Accessory Tray
6718	Pin Plug	Silicone	1 - Pin Plug	4 hours minimum	Accessory Tray
6719	Pin Plug	Silicone	1 - Pin Plug	4 hours minimum	Accessory Tray
6920	Sleeve	Silicone	1 - Sleeve	4 hours minimum	Accessory Tray
6925	Sleeve	Silicone	1 - Sleeve	4 hours minimum	Accessory Tray
5867-2	Anchor Sleeve	Silicone	1 - Anchor Sleeve	4 hours minimum	Accessory Tray
5867AS	Anchor Sleeve	Silicone	1 - Anchor Sleeve	4 hours minimum	Accessory Tray
6043	Cover Anti-stimulator	Silicone	1 - Cover-Anti-stimulator	4 hours minimum	Accessory Tray
6049	Cover Anti-muscle stimulation	Silicone	1 - Cover-Antimuscle stimulation	4 hours minimum	Accessory Tray
6081	Cover Anti-stimulation	Silicone	1 - Cover-antistimulation	4 hours minimum	Accessory Tray
5867-5	Splice Kit	Silicone	1 - Medical Adhesive and cap-tube	4 hours minimum	Accessory Tray
5460	Ace Header	Titanium, polyurethane, silicone	1- Ace Header	24 hours minimum	Accessory Tray
Multi	End Caps	Silicone	2 - End Caps	4 hours minimum	Accessory Tray

*Representative worst case model for small accessory implants, which has been qualified and meets 10993-7:2008/AC:2009 acceptance criteria. Therefore, testing was not required. Reference results section 9.0 for documented results (Tables 133 – 136). The **5866-46** model **represents all small accessories** in Table 18 for the following reasons:

1. Aeration of 48 hours. The 5866-46 and 5866-45 require the most amount of aeration for the product listed in Table 18. However, the 5866-46 contains 4 connector sleeves compared to 1 connector sleeve for the 5866-45. Therefore, the 5866-46 was chosen.

**Representative worst case models for small accessory implants at 1X sterilization. Reference results section 9.0 for testing results (Tables 94 - 97). It was determined that the 6717 pin plugs are not worst case compared to the 5866-46 due to the amount of required aeration and concentration of components. The 6717 pin plugs were still tested and can be used for informational purposes.

Table 19: CRHF Non-Implantable Accessories Based at 1X Sterilization with aeration at minimum of 4 hours

Model	Group Design	Body Diameter	Primary Material Composition	Components	Package Type
***6056**	***Pinch On Tool***	***NA***	***Acetal Homopolymer***	***1 - Pinch on Tool/Rotation Tool***	***Accessory Tray***
5873W	Wrench Kit	NA	Stainless Steel	Hex Wrenches	Accessory Tray
5873C	Service Kit	NA	Stainless Steel	Hex Wrenches	Accessory Tray
6228SLT	Slitter	NA	Stainless Steel	1 - Slitter	Accessory Tray
Torque Clip	Torque Clip	NA	Stainless Steel	1 - Torque Clip	Accessory Tray
***6295**	***Attain Lead Kit***	***NA***	***Polypropylene***	***2 retension clips***	***Accessory Tray***
080118	Adhesive	NA	Silicone	1 - Medical Adhesive and cap-tube	Accessory Tray

*Representative worst case models for non-implantable accessories. Reference results section 9.0 for testing results (6295: Tables 98-101; 6056: Tables 111-112). Both the **6056** and **6295** models can be used to **represent all models in Table 19**. Reason why the 6056 and 6296 models were chosen is as follows:

1. The 6056 model contains acetal homopolymer and the 6295 model contains polypropylene as the primary material composition. All other models in Table 19 contain stainless steel as a primary material composition. Stainless steel has historically been shown to not retain EO/ECH as much as silicone or polypropylene. Model 080118 (medical adhesive) is contained in an aluminum foil tube, which is impenetrable to EO gas. Medical adhesive 080118 is gamma sterilized before it's received and packaged at Medtronic.

Table 20: CRHF Non-Implantable Accessories (Stylets) Based at 1X Sterilization with aeration at minimum of 4 hours

Model	Group Design	Body Diameter	Primary Material Composition	Components	Package Type
6048	Stylet	0.014 in	Stainless Steel	2 stylets, 2 stylet guides	Standard Lead Tray
6057	Stylet	0.014 in	Stainless Steel	2 stylets, 2 stylet guides	Standard Lead Tray
6082	Stylet	0.014 in	Stainless Steel	2 stylets, 2 stylet guides	Standard Lead Tray
***6093**	***Stylet***	***0.016 in***	***Stainless Steel***	***3 stylets, 2 stylet guides***	***Stylet Pouch***
6254	Stylet	0.016 in	Stainless Steel	3 stylets	Stylet Pouch
6282	Stylet	0.014 in	Stainless Steel	3 stylets	Stylet Pouch
6293	Stylet	0.016 in	Stainless Steel	3 stylets	Stylet Pouch
***6052**	***Stylet***	***0.014 in***	***Stainless Steel***	***4 stylets, ACI, Pinch on Tool***	***Standard Lead Tray***
6091	Stylet	0.014 in	Stainless Steel	2 stylets, 2 stylet guides	Standard Lead Tray and Stylet Pouch
6094	Stylet	0.014 in	Stainless Steel	2 stylets, 2 stylet guides	2 stylets, 2 stylet guides
6054	*Stylet*	*0.016 in*	*Stainless Steel*	*3 stylets, 2 stylet*	*Stylet Pouch*

				guides	

*Representative worst case models for non-implantable stylets. Reference results section 9.0 for testing results (6093: Tables 107-110; 6052: Tables 115-122). Both the **6093** and **6052** models can be used to **represent all models in Table 20**. Reason why the 6093 and 6052 models were chosen is as follows:

1. The 6093 and 6054 have the largest body diameters and the same components. Either of the two could be picked. The 6093 was chosen.
2. The 6052 contained the most amount of EO absorbing components.

Table 21: Phased-Out CRHF Accessory Models Not Assessed

Model Numbers		
6984	6996ST	6047
5426	5867-6	2927
6493	5866-34	6981
6081	5867-3	
5441A	5426	
6098	2928	
6054	6245	
6091B	6929	

Table 22: OEM Accessory Models Not Assessed

Model Numbers		
6230UNI	6232ADJ	5019

Table 23: CRHF Accessory Model In Development and Not Qualified for EO Sterilization

Model Number
*4719 Silicone

*Model number is actually silicone and not a part. The silicone will be qualified for EO sterilization according to 10993-7:2008/AC:2009 once qualification testing begins as per product sterilization protocol.

3.4 CRHF TDS Drug Delivery Catheter – Group 4

Table 24: Drug Delivery Catheter at 1X Sterilization with aeration at a Minimum of 4 Hours

Model	Group Design	Primary Material Composition	Package Type
10642/8201	***Drug Delivery Catheter***	***Silicone and Polyurethane***	***DELP Tray***

*Representative worst case model for CRHF Drug Delivery Catheters at 1X Sterilization, which has been qualified and meets 10993-7:2008/AC:2009 acceptance criteria. Therefore, testing was not required. Reference results section 9.0 for documented results (Tables 137 – 140).

4.0 REFERENCES:

Identifier	Title	Internal Repository
ISO 11135-1:2007	*Sterilization of health care products – Ethylene Oxide Part 1: Requirement for development, validation and routine control of a sterilization process for medical devices.*	External standard
EN 556-1: 2001	*Sterilization of medical devices - Requirements for medical devices to be labeled "STERILE".*	
ISO 10993-7: 2008/AC:2009	*Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals.*	
ISO 10993-7: 1995	*Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals.*	

Identifier	Title	Internal Repository
ISO 10993-10:2010	*Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity*	
AAMI TIR19: 1998	*Guidance for ANSI/AAMI/ISO 10993-7:1995, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals*	
Minneapolis Chemical Technologies - REQ-090420-011	*4296, 1X, 2 Hours Aeration Lead, Anchoring Sleeve, 5 Stylet Guides, Torque Wrench, Entire Stylet X4, 4/20/2009 1142*	Stored in Rice Creek Neurological Chemical Technologies Department LIMS
Minneapolis Chemical Technologies - REQ-090421-010	*4296, 4X, , Lead, Anchoring Sleeve, Stylet Guides, Torque Wrench, Entire Stylet X4*	
Minneapolis Chemical Technologies – 20911006	*Lead, Anchor Sleeve. Serial #'s BAA001165R, BAA002517R, BAA001475R, BAA001175R, BAA001177R*	
Minneapolis Chemical Technologies – 21118012	*Lead, Guidewire Guide, Clip, Guidwire Handle, Five Stylets. Serial #'s LFG000129R, LFG000105R, LFG000132R, LFG000125R, LFG000144R*	
Minneapolis Chemical Technologies – 31209013	*Lead, vein lifter, stylet guides, two pinch-on tools, six stylets. Serial #'s BBL000019V, BBL000017V, BBL000016V*	
Minneapolis Chemical Technologies – 31201020	*Lead, vein lifter, stylet guides, two pinch-on tools, six stylets. Serial #'s BBL000024V, BBL000023V, BL000021V*	
Minneapolis Chemical Technologies – 31222001	*Lead, vein lifter, stylet guides, two pinch-on tools, six stylets. Serial #'s BBL000015V, BBL000012V, BBL000011V*	
Minneapolis Chemical Technologies – REQ-090826-007	*10642, 1X Drug Delivery Catheter. Serial #'s: SWR A3725145, SWR A3725152, SWR A3725155*	
Minneapolis Chemical Technologies – REQ-090826-008	*10642, 3X Drug Delivery Catheter. Serial #'s: SWR A3725174, SWR A3725175, SWR A3725179*	
JH033041FR	*Sterilization Qualification Report for the Medtronic Model 4076 Leads Sterilized and Aerated in the 3M 5XL Steri-Vac™ 100% EtO Sterilizers and XL Aerators at the Medtronic Puerto Rico Inc. (MPRI) Facility*	Documentum "mitdoc2
JH032241FR	*Aeration Process Qualification Protocol for Japanese-Distributed Medtronic Lead & Accessory Products Sterilized and Aerated in the 3M 5XL Steri-Vac™ 100% EtO Sterilizers and XL Aerators at the Medtronic-Puerto Rico, Inc. (MPRI) and Rice Creek (RC)Facility*	
Certification 1119, Issue Level 3N	*Cardiac Rhythm Disease Management- Therapy Delivery Lead and Accessory Certification—Rice Creek*	
Certification 1119, Issue Level 3L	*Cardiac Rhythm Disease Management- Therapy Delivery Lead and Accessory Certification—Rice Creek*	
Certification 1119, Issue Level 3K	*Cardiac Rhythm Disease Management- Therapy Delivery Lead and Accessory Certification—Rice Creek*	
BSH110811MM	*Tolerable Contact Limit Extraction Time and Acceptance Criteria Update for ANSI/AAMI/ISO 10993-7:2008*	
Sterilization Certification Report 1125	*Physical Profile Requalification Report of the 3M 5XL/5XLe Steri-Vac™ 100% EtO Sterilizers and XL/XLe Aerators at the Rice Creek Manufacturing Facility*	
DL991732	*Sterilization Qualification Report for the ESTC 5038 Leads in the 3M 5XL Steri-Vac™ 100% EtO Sterilizers at MPRI*	
BH021831FR	*Sterilization Qualification Report for the Attain Bi-polar 4194 Lead*	
DL952821.A	*European Sterilization Qualification Report for Brady/Tachy Leads, ICD's, IPG's and Pacing Accessories in 100% EtO 3M 5XL Sterilizers*	
BSH111461PC	*Medtronic CRHF Therapy Delivery System Product Compliance to ANSI/AAMI/ISO 10993-7:2008/AC:2009*	
BL0022505	*Study Report – Sterilization Qualification for NayaMed Lead Model*	MRCS

Identifier	Title	Internal Repository
	NDX102	
BL0021882	*Product Sterilization Qualification Report for the Implantable Intravascular Drug Delivery Catheter Medtronic Model 10642/8201, Sterilized and Aerated in the 3M™ 5XLe Steri-Vac™ 100% EtO Sterilizers and XL/XLe Aerators at the Medtronic- Rice Creek Facility*	
BL0020404	*Product Sterilization Qualification Protocol for the Implantable Intravascular Drug Delivery Catheter Medtronic Model 10642, Sterilized and Aerated in the 3M™ 5XLe Steri-Vac™ 100% EtO Sterilizers and XL/XLe Aerators at the Medtronic- Rice Creek Facility*	
BL0021932	*Product Qualification Report for the Medtronic Sevento™ Series Model lead designs Sterilized and Aerated in the 3M 5XLe Steri-Vac 100% EtO Sterilizers and XL(e) Aerators at the Medtronic Rice Creek (RC) Facility and MPROC Facility*	
MDT1897325	*Compliance to ISO 10993-7:2008 with Current Chemical Technology Process*	
BL0027436	*Sterilization Report for the 6947M Leads Product Family*	
BL0024585	*Product Sterilization Qualification Report for the Medtronic 6935M and NayaMed NDX401 Single Coil Lead Product Family*	
BL0023825	*Product Sterilization Qualification Report for the 6944A Sprint Quattro Lead Product Family*	
BL0025829	*Product Sterilization Qualification Report for 6946M Sprint Quattro® Lead Product Family*	
BL0021882	*Product Sterilization Qualification Report for the 8201 Implantable Intravascular Drug Delivery Catheter*	
CSS-0901-0001-0019	*Ethylene Oxide Sterilizer System Equipment and Process Equivalency*	Agile
CSS-0911-XXXX-0002*	*Sterilant Residue Analysis*	
CSS-0901-0001-0008	*Development, Validation, and Requalification of the 100% EO Sterilizer Systems*	
CSS-0501-XXXX-0024	*Abbreviations, Acronyms and Definitions Used in Global Sterilization and Microbiology Documentation*	
CRM-0902-0001	*Internal Ethylene Oxide Sterilization*	
CSS-1801-XXXX-0005	*Operation of the 100% Ethylene Oxide Sterilizer System*	
091033-050 (Issues 131 and 132)	*Product Sterilization – 30 Minute EO Exposure Process at Rice Creek*	CRHF MSP Manufacturing Documentation
CHEMWI10219	*Residual EO and ECH on Sterilized Devices*	MRCS (NPP)
R000700, Rev. 2.0	*Model 6947 Lead Irritation Testing*	Enovia
R000743, Rev. 2.0	*Model 4195 Lead Irritation Testing*	
R000685	*Rev. 2.0, Model 7927 Lead Irritation Testing Biological Evaluation Report.*	
168651	*Gas – Sterilant, Ethylene Oxide*	

*Instruction CSS-0911-XXXX-0002 has been obsoleted since testing was performed for this report; however, it is being left within the “Reference” Section for completeness.

5.0 ABBREVIATIONS/ACRONYMS/DEFINITIONS:

Abbreviation or Acronym	Definition of Abbreviation of Acronym
AAMI	Association for the Advancement of Medical Instrumentation
Aeration	Part of the sterilization process during which ethylene oxide and/or its reaction

Abbreviation or Acronym	Definition of Abbreviation of Acronym
	products desorb from the medical device until predetermined levels are reached NOTE: This may be performed within the sterilizer and/or in a separate chamber or room
ANSI	American National Standards Institute
CEN	Comité Européen de Normalisation
CRHF	Cardiac Rhythm Heart Failure
DELP	Dual-Entry Leads Packaging
ECH	Ethylene chlorohydrin
EG	Ethylene glycol
EN	European Standard (Europäische Norm)
Ethylene Oxide (EO)	Ethylene Oxide is a colorless gas at room temperature, having a sweet odor at concentrations of 500-700 ppm. It is used as a sterilizing agent. The chemical formula is C_2H_4O.
EO Sterilant Residuals	By-products of EO. It is required that residuals be monitored after sterilization in accordance to regulatory guidelines. Residuals that have imposed limits are ethylene oxide (EO) and ethylene chlorohydrin (ECH). Historically, ethylene glycol (EG) was monitored, but recent risk assessment studies have demonstrated that when EO residues are controlled as required, it is unlikely that biologically significant residues of EG would be present.
Exhaustive Extraction	Extraction until the amount of EO or ECH in a subsequent extraction is less than 10% of that detected in the first extraction, or until there is no analytically significant increase in the cumulative residue levels detected. NOTE: As it is not possible to demonstrate the exhaustive nature of residual recovery, the definition of exhaustive extraction adopted is as above.
Forced Heat Aeration	Aeration that is to be performed in a “cold aerator” (room temperature) after the required 10 minute air flush in the sterilizer is completed to simulate worst-case conditions. Aeration times will begin when the aerator door is closed and the “START” button is pushed. The aeration start/stop times are based upon the specified EXACT aeration time that has elapsed.
ISO	International Organization for Standardization
Load Configuration	Totality of attributes defining the presentation of the product to the sterilization process. This configuration includes 1) the orientation of the product within the primary package; 2) the quantity and orientation of the primary package(s) within the secondary and tertiary package; 3) the quantity, orientation, and placement of the tertiary packages on the sterilizer pallets (or within the carriers); and 4) the quantity and placement of the pallets (or carriers) within the vessel or area.
µg	micrograms
mg	milligrams
MPROC	Medtronic Puerto Rico Operations Center
NA	Not Applicable
OEM	Original Equipment Manufacturer
ppm	Parts per million
Ref.	Reference
StAR System	Sterilization Automated Release System
Sterility Assurance Level (SAL)	Probability of a single viable microorganism occurring on an item after sterilization. NOTE: The term SAL takes a quantitative value, generally 10^{-6} or 10^{-3}. When applying this quantitative value to assurance of sterility, an SAL of 10^{-6} has a lower value but provides a greater assurance of sterility than an SAL of 10^{-3}.
TCL	Tolerable Contact Limit
Reference work instruction CSS-0501-XXXX-0024 for a comprehensive list of sterilization abbreviations, acronyms, and definitions used in this report.	

6.0 MATERIALS & EQUIPMENT:

6.1 Sterilizer, Aerator and Process Descriptions:

The description of the 3M™ 5XLe Steri-Vac™ 100% EO sterilizer, 3M™ XL(e) aerator and the Donaldson EtO abator system are clarified and documented in sterilization work instruction CSS-0901-0001-0019 (ref. section 4.0). The process description and parameters of the 3M™ 5XLe Steri-Vac™ 100% EO sterilizer, 3M™ XL(e) aerator and the Donaldson EO abator system are also clarified and documented in CSS-0901-0001-0019 (ref. section 4.0).

6.2 Sterilizer and Aerator Validation & Calibration:

The 5XLe sterilizer and XL(e) aerator validation procedures are performed per the instructions called-out in CSS-0901-0001-0008, CSS-0901-0001-0019 and documented in Certification 1125 (ref. section 4.0) for Rice Creek. Calibration of all sterilizers, aerators and the associated controlling and monitoring equipment is specified in Medtronic Minneapolis Metrology and Equipment Support procedures.

6.3 Sterilizer and Aerator Equivalency:

Medtronic-owned 3M™ sterilizer and aeration vessels are considered equivalent per Sterilization Services procedure CSS-0901-0001-0019 (ref. section 4.0). Every 3M™ 5XLe 100% EO sterilizer and XL(e) aerator system is provided with a "3M 5XL/5XLe Steri-Vac™ 100% EO Sterilizer and XL/XLe EO Aerator Equivalency Checklist". The equivalency checklist is documented per CSS-0901-0001-0019 (ref. section 4.0). The equivalency checklist certifies that the sterilizer and aerator systems meet all of the equivalency requirements.

6.4 EO Gas Supply:

The 3M™ Steri-Vac™ 127 gram cartridges were used for this qualification study. All cartridges used were received and inspected in accordance with 168651 (ref. section 4.0), and were from manufacturing lots inspected to be $\geq$ 99.9% pure EO.

6.5 DELP Reference Product:

A maximum of seventy-four (74) DELP reference product units were utilized, each containing appropriate dunnage lead and accompanying accessories as per manufacturing process 091033-050 (ref. section 4.0).

6.6 Standard Lead Tray Reference Product:

A maximum of fifty-four (54) standard lead reference product units were utilized, each containing appropriate dunnage lead and accompanying accessories as per manufacturing process 091033-050 (ref. section 4.0).

6.7 Pacing Accessories Reference Product:

A maximum of four-hundred and eighty-three (483) pacing accessory reference product units were utilized, each containing appropriate dunnage as per manufacturing process 091033-050 (ref. section 4.0).

6.8 Stylet Pouch Reference Product:

A maximum of two-hundred (200) stylet pouch reference product units were utilized, each containing appropriate dunnage as per manufacturing process 091033-050 (ref. section 4.0).

7.0 GENERAL:

7.1 Responsibility:

7.1.1 Medtronic- MPROC-Villalba and CRHF Therapy Delivery Manufacturing:

- Verified that expected sterilization process conditions did not affect product and package quality or functionality.
- Confirmed that product was qualified for sterilization at the specified process parameters.
- Manufacturing and sterile packaging of product.

7.1.2 Medtronic- Chemical Technologies:

- Performed EO/ECH and TCL extraction testing on chosen representative CRHF legacy product models called-out within protocol BSH111461PC (ref. section 4.0) to ensure compliance with residual requirements stated in ISO 10993-7: 2008/AC:2009 (ref. section 4.0).

7.1.3 Medtronic- CRHF Sterilization Services:

- Sterilization and aeration processing of test samples.
- Performed inspection of sterilization process data, if applicable.
- Analyzed results for compliance to 10993-7:2008/AC:2009 (ref. section 4.0).

7.2 Sterility Assurance Level (SAL):

The CRHF Medtronic TDS leads, accessories and adaptors are terminally sterilized to a SAL of 10^{-6}, as defined by ISO 11135-1 and required by EN 556-1 (ref. section 4.0) for release as 'sterile'.

7.3 Product Process Control:

Lead components or sub-assemblies are obtained from Medtronic approved suppliers. Final manufacture, assembly and packaging processes are performed at Medtronic per the manufacturing procedure. All assembly and packaging components and processes, material/component suppliers and facilities utilized for the assembly of all routine production and future test sample devices must be identical or equivalent to the test sample devices utilized for this report.

8.0 PROCEDURE:

Sterilant residual testing was performed using a worst-case residual testing methodology by following CSS-1801-XXXX-0005 (ref. section 4.0) upon selected representative worst case models per protocol BSH111461PC (ref. section 4.0). The worst case residual testing encompasses the most challenging sterilization parameters at the manufacturing facilities that could affect the EO residuals in the products. This includes the following:
Aeration occurred in an aeration chamber versus the sterilization chamber. Aeration in an aerator simulates a worst case aeration condition since the aerator that is initially at ambient temperature requires approximately 20-30 minutes to reach the required set point temperature.

- The minimum aeration time allowed by production on leads was used for testing as the minimum aeration time will allow for higher residuals.
- The aeration process was started in a cold aeration chamber from the time the aerator was started versus the start of aeration once a chamber achieves the minimum aeration temperature of 44°C.
- The samples were frozen between cycles to minimize the amount of off gassing between cycles.

All Sterilant residual testing analysis was conducted per procedure CHEMWI10219 (ref. section 4.0) by Chemical Technologies lab, located at the Medtronic Rice Creek facility in Minneapolis, MN. See section 10.0 of this report for deviations to protocol BSH111461PC (ref section 4.0).

9.0 RESULTS VS. ACCEPTANCE CRITERIA:

Tables 25-48 exhibit EO/ECH and TCL results for the selected worst case "High Voltage" test models. Tables 49-93 exhibit EO/ECH and TCL results for the selected worst case "Low Voltage" test models. Tables 91-133 exhibit EO/ECH and TCL results for the selected worst case "Low Voltage" test models. Tables 137-140 exhibit EO/ECH and TCL results for the selected worst case "TDS Drug Catheter" test model. Table 141 exhibits the sterilization parameters that were followed for all tested product within this report.

Note: "Blank" control samples and results are only available for the selected representative worst case models that were tested as per protocol BSH111461PC (ref. section 4.0) since it was previously not a requirement.

9.1 High Voltage EO/ECH and TCL Results

9.1.1 *7927 Lead Model "Load configuration I/I – DELP Trays"* – ref. BL0021932 and MDT1897325 (ref. section 4.0)

Table 25: Sterilant Residual EO and ECH Analysis Results for the Permanent Contact Portions of the 7927-65 Lead (Exhaustive Extraction) extracted at 37°C

Sterilant Residual Specification	Components Extracted (pooled together)	Residual Type	Acceptance Criteria	*1X Results – 2 hrs. forced heat		*3X Results – 2,2,2 hrs. forced heat		*4X Results – ,2,2,2 hrs. forced heat	
				EO (mg)	Pass/Fail	EO (mg)	Pass/Fail	EO (mg)	Pass/Fail
Dose for first 24 hours not to exceed	*Lead and Anchoring Sleeve*	EO	4 mg	0.52	Pass	1.20	Pass	0.60	Pass
Dose for first 30 days not to exceed			60 mg	0.66	Pass	1.54	Pass	0.81	Pass
Lifetime dose not to exceed**			2500 mg	0.66	Pass	1.54	Pass	0.81	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.1 mg/day	2.6×10^{-05}	Pass	6.2×10^{-05}	Pass	3.2×10^{-05}	Pass
				ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail
Dose for first 24 hours not to exceed		ECH	9 mg	0.02	Pass	0.016	Pass	0.004	Pass
Dose for first 30 days not to exceed			60 mg	0.02	Pass	0.016	Pass	0.004	Pass
Lifetime dose not to exceed**			10,000 mg	0.02	Pass	0.016	Pass	0.004	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.4 mg/day	8.2×10^{-07}	Pass	6.4×10^{-07}	Pass	1.7×10^{-07}	Pass

*Reference Attachments 1, 3, 5 for EO/ECH residual results.

**Medtronic Chemical Technologies exhaustively extracts until the last residual extraction result is less than 10% of the first extraction result (taken at 24 hours), which represents the lifetime dose. Based on the results above, the reported 30 day dose is the same as the lifetime dose.

Table 26: Limited Exposure EO and ECH Residual Results for the 7927-65 Lead extracted at 37°C.

Residual Type	EO Residual Specification	Components Extracted (pooled together)	Acceptance Criteria	*1X Results – 2 hrs. forced heat		*3X Results – 2,2,2 hrs. forced heat		*4X Results – 2,2,2,2 hrs. forced heat	
				Result (mg)	Pass /Fail	Result (mg)	Pass /Fail	Result (mg)	Pass /Fail
EO	Dose for first 24 hours not to exceed (average daily dose)	Stylets, Vein Lifter, Pinch On Tool, Pin caps, Sleeves, Rotaton Tool	4 mg	0.23	Pass	0.85	Pass	0.44	Pass
ECH	Dose for first 24 hours not to exceed (average daily dose)		9 mg	0.006	Pass	0.006	Pass	0.006	Pass

*Reference Attachments 1, 3, 5 for EO/ECH residual results.

Table 27: 7927-65 Individual Component Surface Areas

Lead Components	Surface Area (cm^2)	Quantity	Total Surface Area (cm^2)
Lead and Anchoring Sleeve -	74.27	1	74.27
Vein lifter - 103548001	11.53	1	11.53
Pin Caps - 117921001	7.55	2	15.1
Stylet Assembly - 136529002	10.42	2	20.84
Stylet Assembly - 404028019	9.99	2	19.98
Stylet Assembly – 404028004	10.02	1	10.02
Pinch On Tool - 800471001	28.37	1	28.37

Table 28: EO Tolerable Contact Limit for the 7927-65 Leads extracted at 37°C

Device Exposure Category	# Times Sterilized	*A* (cm^2)	TCL (µg/cm^2)	$m_{dev, BSC}$ = *A* x TCL (µg)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev, BSC}$ = *A* x TCL (mg)	Result $m_{dev, BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	74.27*	10	742.7	≤ 0.7427	0.75	***Fail	2
	3x					0.43	Pass	4
	4x					0.51	Pass	6
Limited**	1x	105.84**		1058.4	≤ 1.0584	0.23	Pass	1
	3x					0.85	Pass	3
	4x					0.44	Pass	5

*The "Lead" and "Anchoring Sleeve" were extracted using the exhaustive method at 37C. The surface calculation shown is derived by combining these component portions together; see Table 27.

** The "Vein lifter", "stylet assemblies", "pinch on tool", "pin caps" and "vein lifter" component portions were pooled together and extracted using the "simulated use" method at 37C for 1 hour. Therefore, the surface calculation shown is derived by combining these component portions together; see Table 27.

***The requirements of ISO 10993-7 (ref. section 4.0) clearly states that both sterilant residual levels and tolerable contact limits must be met. Should the tolerable contact limit not be achieved, irritation testing may be performed per ISO 10993-10 (ref. section 4.0). Irritation testing was performed on the 1X 7927-65 samples to ensure product is non-irritating after EO sterilization. The irritation testing was performed at NAMSA through the facilitation of Medtronic Physiological Research Laboratory Facility. The biological evaluation report R000685 (ref. section 4.0) shows that the 7927-65 lead does not exhibit any evidence of significant irritation as processed for this application. Therefore, the 7927-65 lead exhibited a score of less than 1.0 for irritation as specified in ISO 10993-10 (ref. section 4.0).

Table 29: ECH Tolerable Contact Limit for the 7927-65 Leads extracted at 37°C

Device Exposure Category	# Times Sterilized	*A* (cm^2)	TCL (mg/cm^2)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,BSC}$ = *A* x TCL (mg)	Result $m_{dev,BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	74.27*	5	≤ 371.35	0.030	Pass	2
	3x				0.014	Pass	4
	4x				0.011	Pass	6
Limited**	1x	105.84**		≤ 529.2	0.006	Pass	1
	3x				0.006	Pass	3
	4x				0.006	Pass	5

*The "Lead" and "Anchoring Sleeve" were extracted using the exhaustive method at 37C. The surface calculation shown is derived by combining these component portions together; see Table 27.
** The "Vein lifter", "stylet assemblies", "pinch on tool", "pin caps" and "vein lifter" component portions were pooled together and extracted using the "simulated use" method at 37C for 1 hour. Therefore, the surface calculation shown is derived by combining these component portions together; see Table 27.

9.1.2 6937A Lead Model "Load Configuration A/A – Standard Lead Trays"

Table 30: Sterilant Residual EO and ECH Analysis Results for the Permanent Contact Portions of the 6937A-100 model (Exhaustive Extraction)

Sterilant Residual Specification	Components Extracted (pooled together)	Residual Type	Acceptance Criteria	*1X Results – 12 hrs. forced heat		**2X Results – 12 and 14 hrs. forced heat		***3X Results – 12,14,14 hrs. forced heat	
				EO (mg)	Pass/Fail	EO (mg)	Pass/Fail	EO (mg)	Pass/Fail
Dose for first 24 hours not to exceed	Lead and Anchoring Sleeve	EO	4 mg	0.5	Pass	0.3	Pass	0.4	Pass
Dose for first 30 days not to exceed			60 mg	0.6	Pass	0.3	Pass	0.4	Pass
Lifetime dose not to exceed****			2500 mg	0.6	Pass	0.3	Pass	0.4	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. section ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.1 mg/day	2.6×10^{-05}	Pass	1.3×10^{-05}	Pass	1.6×10^{-05}	Pass
Blank Control – No EO exposure			N/A	0.005	NA				
				ECH (mg)	Pass/Fail	ECH (mg)	ECH (mg)	Pass/Fail	Pass/Fail
Dose for first 24 hours not to exceed		ECH	9 mg	0.03	Pass	0.02	Pass	0.02	Pass
Dose for first 30 days not to exceed			60 mg	0.03	Pass	0.02	Pass	0.02	Pass
Lifetime dose not to exceed****			10,000 mg	0.03	Pass	0.02	Pass	0.02	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. section ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.4 mg/day	1.3×10^{-06}	Pass	8.7×10^{-07}	Pass	6.8×10^{-07}	Pass
Blank Control – No EO			N/A	0.001	NA				

exposure										

* Reference Attachment 71 **Reference Attachment 73 ***Reference Attachment 75
****Medtronic Chemical Technologies exhaustively extracts until the last residual extraction result is less than 10% of the first extraction result (taken at 24 hours), which represents the lifetime dose. Based on the results above, the reported 30 day dose is the same as the lifetime dose.

Table 31: Limited Exposure EO and ECH Residual Results for the 6937A-100 model (Simulated Use)

Residual Type	EO Residual Specification	Extraction Temperature	Components Extracted (pooled together)	Acceptance Acceptance Criteria	*1X Results – 12 hrs. forced heat		**2X Results – 12,14 hrs. forced heat		***3X Results – 12,14,14 hrs. forced heat	
					Result (mg)	Pass /Fail	Result (mg)	Pass /Fail	Result (mg)	Pass /Fail
EO	Dose for first 24 hours not to exceed (average daily dose)	37°C	Stylet Assembly and Vein Lifter	4 mg	0.02	Pass	0.01	Pass	0.01	Pass
	Blank Control – No EO exposure			N/A	0.01	Pass				
	Dose for first 24 hours not to exceed (average daily dose	25°C	Stylet Guide	4 mg	0.005	Pass	0.005	Pass	0.005	Pass
	Blank Control – No EO exposure			N/A	0.005	Pass				
ECH	Dose for first 24 hours not to exceed (average daily dose)	37°C	Stylet Assembly and Vein Lifter	9 mg	0.01	Pass	0.01	Pass	0.01	Pass
	Blank Control – No EO exposure			N/A	0.01	Pass				
	Dose for first 24 hours not to exceed (average daily dose	25°C	Stylet Guide	9 mg	0.005	Pass	0.005	Pass	0.005	Pass
	Blank Control – No EO exposure			N/A	0.005	Pass				

* Reference Attachment 71 **Reference Attachment 73 ***Reference Attachment 75

Table 32: 6937A-100 Individual Component Surface Areas

Components	Surface Area (cm^2)	Quantity	Total Surface Area (cm^2)
Lead and Anchoring Sleeve – 502450303	84.34	1	84.34
Stylet Assembly - 404247004	15.26	4	61.04
Stylet Assembly - 404028008	13.86	2	27.72
Stylet Guide - 105115001	2.58	1	2.58
Vein Lifter - 103548001	11.48	1	11.48

Table 33: EO Tolerable Contact Limit for the 6937A-100 Model

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL ($\mu g/cm^2$)	$m_{dev,BSC}$ = *A* x TCL (µg)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,BSC}$ = *A* x TCL (mg)	Result $m_{dev,BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	84.34*	10	843.4	≤ 0.8434	0.5	Pass	72
	2x						0.2	Pass	74
	3x						0.3	Pass	76
Limited **	1x		100.24**		1002.4	≤ 1.0024	0.02	Pass	71
	2x						0.01	Pass	73
	3x						0.01	Pass	75
Limited ***	1x	25°C	2.58		25.8	≤ 0.0258	0.005	Pass	71
	2x						0.005	Pass	73
	3x						0.005	Pass	75

*****The "Lead and Anchoring Sleeve" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these component portions together; see Table 32.
**The "Stylet Assembly" and "Vein Lifter" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 32.
***The "Stylet Guide" was extracted using the simulated method at 25°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 32.

Table 34: ECH Tolerable Contact Limit for the 6937A-100 Model

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (mg/cm^2)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,BSC}$ = *A* x TCL (mg)	Result $m_{dev,BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	84.34*	5	≤ 421.7	0.03	Pass	72
	2x					0.01	Pass	74
	3x					0.01	Pass	76
Limited **	1x		100.24**		≤ 501.2	0.01	Pass	71
	2x					0.01	Pass	73
	3x					0.01	Pass	75
Limited ***	1x	25°C	2.58		≤ 12.9	0.005	Pass	71
	2x					0.005	Pass	73
	3x					0.005	Pass	75

*****The "Lead and Anchoring Sleeve" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these component portions together; see Table 32.
**The "Stylet Assembly" and "Vein Lifter" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 32.
***The "Stylet Guide" was extracted using the simulated method at 25°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 32.

9.1.3 6721L Patch Model "Load Configuration F – Patch Leads Pouch"

Table 35: Sterilant Residual EO and ECH Analysis Results for the Permanent Contact Portions of the 6721L patch (Exhaustive Extraction)

Sterilant Residual Specification	Components Extracted	Residual Type	Acceptance Criteria	*1X Results – 4 hrs. forced heat		**3X Results – 4,8,8 hrs. forced heat		***4X Results – 4,8,8,8 hrs. forced heat	
				EO (mg)	Pass/Fail	EO (mg)	Pass/Fail	EO (mg)	Pass/Fail
Dose for first 24 hours not to exceed	Patch	EO	4 mg	0.03	Pass	0.02	Pass	0.02	Pass
Dose for first 30 days not to exceed			60 mg	0.05	Pass	0.04	Pass	0.03	Pass
Lifetime dose not to exceed****			2500 mg	0.05	Pass	0.04	Pass	0.03	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.1 mg/day	1.8×10^{-06}	Pass	1.4×10^{-06}	Pass	1.4×10^{-06}	Pass
Blank Control – No EO exposure			N/A	0.01	N/A				
				ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail
Dose for first 24 hours not to exceed		ECH	9 mg	0.06	Pass	0.03	Pass	0.02	Pass
Dose for first 30 days not to exceed			60 mg	0.08	Pass	0.03	Pass	0.02	Pass
Lifetime dose not to exceed****			10,000 mg	0.08	Pass	0.03	Pass	0.02	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.4 mg/day	3.0×10^{-06}	Pass	1.4×10^{-06}	Pass	6.8×10^{-07}	Pass
Blank Control – No EO exposure			N/A	0.001	N/A				

*Reference Attachment 65. **Reference Attachment 67. ***Reference Attachment 69.

****Medtronic Chemical Technologies exhaustively extracts until the last residual extraction result is less than 10% of the first extraction result (taken at 24 hours), which represents the lifetime dose. Based on the results above, the reported 30 day dose is the same as the lifetime dose.

Table 36: 6721L Individual Component Surface Areas

Components	Surface Area (cm^2)	Quantity	Total Surface Area (cm^2)
Patch – 501844401	272.12	1	272.12

Table 37: EO Tolerable Contact Limit for the 6721L patch

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL ($\mu g/cm^2$)	$m_{dev,BSC}$ = *A* x TCL (µg)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,BSC}$ = *A* x TCL (mg)	Result $m_{dev,BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	272.12*	10	2721.2	≤ 2.7212	0.03	Pass	66
	3x						0.02	Pass	68
	4X						0.02	Pass	70

*****The "Patch" was extracted using the exhaustive method at 37°C.

Table 38: ECH Tolerable Contact Limit for the 6721L patch

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (mg/cm^2)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev, BSC}$ = *A* x TCL (mg)	**Result** $m_{dev, BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	272.12*	5	≤ 1360.6	0.13	Pass	66
	3x					0.07	Pass	68
	4X					0.04	Pass	70

*****The "Patch" was extracted using the exhaustive method at 37°C.

9.1.4 6947-100 Lead Model "Load Configuration A/A – Standard Lead Trays"

Table 39: Sterilant Residual EO and ECH Analysis Results for the Permanent Contact Portions of the 6947-100 model (Exhaustive Extraction)

Sterilant Residual Specification	Components Extracted (pooled together)	Residual Type	Acceptance Criteria	*1X Results – 8 hrs. forced heat		**3X Results – 8,8,8 hrs. forced heat		***4X Results – 8,8,8,8 hrs. forced heat	
				EO (mg)	Pass/Fail	EO (mg)	Pass/Fail	EO (mg)	Pass/Fail
Dose for first 24 hours not to exceed	Lead and Anchoring Sleeve and Pin Cap	EO	4 mg	1.62	Pass	1.59	Pass	1.22	Pass
Dose for first 30 days not to exceed			60 mg	2.17	Pass	1.84	Pass	1.67	Pass
Lifetime dose not to exceed****			2500 mg	2.17	Pass	1.84	Pass	1.67	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.1 mg/day	0.0	Pass	0.0	Pass	6.70×10^{-05}	Pass
Blank Control – No EO exposure			N/A	0.02	NA				
				ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail	EO (mg)	Pass/Fail
Dose for first 24 hours not to exceed		ECH	9 mg	7.33×10^{-02}	Pass	5.82×10^{-02}	Pass	2.75×10^{-02}	Pass
Dose for first 30 days not to exceed			60 mg	7.33×10^{-02}	Pass	5.82×10^{-02}	Pass	2.75×10^{-02}	Pass
Lifetime dose not to exceed****			10,000 mg	7.33×10^{-02}	Pass	5.82×10^{-02}	Pass	2.75×10^{-02}	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.4 mg/day	2.9×10^{-06}	Pass	2.33×10^{-06}	Pass	1.10×10^{-06}	Pass
Blank Control – No EO exposure			N/A	2.11×10^{-02}	NA				

*Reference Attachment 77. **Reference Attachment 79. ***Reference Attachment 81.

****Medtronic Chemical Technologies exhaustively extracts until the last residual extraction result is less than 10% of the first extraction result (taken at 24 hours), which represents the lifetime dose. Based on the results above, the reported 30 day dose is the same as the lifetime dose.

Table 40: Limited Exposure EO and ECH Residual Results for the 6947-100 model (Simulated Use)

Residual Type	EO Residual Specification	Extraction Temperature	Components Extracted (pooled together)	Acceptance Criteria	*1X Results – 8 hrs. forced heat		**3X Results – 8,8,8 hrs. forced heat		***4X Results – 8,8,8,8 hrs. forced heat	
					Result (mg)	Pass /Fail	Result (mg)	Pass /Fail	Result (mg)	Pass /Fail
EO	Dose for first 24 hours not to exceed (average daily dose)	37°C	Stylet Assembly and Vein Lifter	4 mg	2.51×10^{-02}	Pass	3.27×10^{-02}	Pass	5.08×10^{-02}	Pass
	Blank Control – No EO exposure			N/A	1.41×10^{-02}	Pass				
	Dose for first 24 hours not to exceed (average daily dose	25°C	Stylet Guide and Pinch-On Tool	4 mg	2.46×10^{-02}	Pass	1.59×10^{-02}	Pass	1.69×10^{-02}	Pass
	Blank Control – No EO exposure			N/A	9.40×10^{-03}	NA				
ECH	Dose for first 24 hours not to exceed (average daily dose)	37°C	Stylet Assembly and Vein Lifter	9 mg	1.59×10^{-02}	Pass	3.53×10^{-02}	Pass	1.62×10^{-02}	Pass
	Blank Control – No EO exposure			N/A	1.62×10^{-02}	Pass				
	Dose for first 24 hours not to exceed (average daily dose	25°C	Stylet Guide and Pinch-On Tool	9 mg	1.06×10^{-02}	Pass	1.06×10^{-02}	Pass	1.08×10^{-02}	Pass
	Blank Control – No EO exposure			N/A	1.08×10^{-02}	NA				

*Reference Attachment 77. **Reference Attachment 79. ***Reference Attachment 81.

Table 41: 6947-100 Individual Component Surface Areas

Components	Surface Area (cm^2)	Quantity	Total Surface Area (cm^2)
Lead and Anchor Sleeve - 502731503	112.13	1	112.13
Anchor Sleeve – 184128-004	4.77	3	14.31
Stylet Assembly - 404247004	15.26	2	30.52
Stylet Assembly - 404028008	13.86	2	27.72
Stylet Guide - 105115001	2.58	1	2.58
Vein Lifter - 103548001	11.48	1	11.48
Pin Cap - 117921001	7.56	2	15.12
Pinch-On-Tool – 800471001	28.37	2	56.74

Table 42: EO Tolerable Contact Limit for the 6947-100 Model

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL ($\mu g/cm^2$)	$m_{dev, BSC}$ = *A* x TCL (µg)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev, BSC}$ = *A* x TCL (mg)	Result $m_{dev, BSC}$ (mg)	Pass/Fail	Attachment
Permanent	1x	37°C	141.56*	10	1415.6	≤ 1.4156	1.48	Fail****	78
	3x						1.75	Fail****	80
	4x						1.46	Fail****	82
Limited	1x		69.72**		697.2	≤ 0.6972	0.03	Pass	77
	3x						0.03	Pass	79
	4x						0.05	Pass	81
Limited	1x	25°C	59.32***		593.2	≤ 0.5932	0.02	Pass	77
	3x						0.04	Pass	79
	4x						0.01	Pass	81

*The "Lead and Anchoring Sleeve" and "Pin-Cap" were extracted using the exhaustive 24 hour extraction method at 37°C. The 8 hour extraction method was not part of ISO 10993-7 at the time testing was performed. The surface calculation shown is derived by combining these component portions together; see Table 41.
**The "Stylet Assembly" and "Vein Lifter" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 41.
***The "Stylet Guide" and "Pinch-On Tools" were extracted using the simulated method at 25°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 41.

****All requirements must be met following single or multiple exposure(s) to an EO sterilization process. The 1X, 3X and 4X samples did not meet the tolerable contact limit requirements stated in ISO 10993-7:2008/AC:2009 (ref. section 4.0) for EO, however did meet the requirements for ECH. The requirements of ISO 10993-7:2008/AC:2009 clearly states that both sterilant residual levels and tolerable contact limits must be met. Should the tolerable contact limit not be achieved, irritation testing may be performed per ISO 10993-10 (ref. section 4.0). As the tolerable contact limit was not met, irritation testing was performed at the Medtronic Physiological Research Facility (PRL) and NAMSA. Biological evaluation report R000700 (ref. section 4.0) shows that the 6947-100 lead does not exhibit any evidence of significant irritation as processed for this application with a score of 0.0. Therefore, the 6947-100 does not exhibit irritation and is acceptable as per ISO 10993-10 (ref. section 4.0).

Table 43: ECH Tolerable Contact Limit for the 6947-100 Model

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (mg/cm^2)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev, BSC}$ = *A* x TCL (mg)	Result $m_{dev, BSC}$ (mg)	Pass/Fail	Attachment
Permanent	1x	37°C	141.56*	5	≤ 707.8	0.04	Pass	78
	3x					0.02	Pass	80
	4x					0.02	Pass	82
Limited	1x		69.72**		≤ 348.6	0.02	Pass	77
	3x					0.02	Pass	79
	4x					0.02	Pass	81
Limited	1x	25°C	59.32***		≤ 296.6	0.01	Pass	77
	3x					0.01	Pass	79
	4x					0.01	Pass	81

*The "Lead and Anchoring Sleeve" and "Pin-Cap" were extracted using the exhaustive 24 hour extraction method at 37°C. The 8 hour extraction method was not part of ISO 10993-7 at the time testing was performed. The surface calculation shown is derived by combining these component portions together; see Table 41.
**The "Stylet Assembly" and "Vein Lifter" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 41.
***The "Stylet Guide" and "Pinch-On Tools" were extracted using the simulated method at 25°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 41.

9.1.5 6996SQ-85 Lead Model "Load Configuration A/A – Standard Lead Trays"

Table 44: Sterilant Residual EO and ECH Analysis Results for the Permanent Contact Portions of the 6996SQ-85 Lead (Exhaustive Extraction)

Sterilant Residual Specification	Components Extracted (pooled together)	Residual Type	Acceptance Criteria	*1X Results – 4 hrs. forced heat		**3X Results – 4, 8, 8 hrs. forced heat		***4X Results – 4,8,8,8 hrs. forced heat	
				EO (mg)	Pass/Fail	EO (mg)	Pass/Fail	EO (mg)	Pass/Fail
Dose for first 24 hours not to exceed	*Lead and Anchoring Sleeve*	EO	4 mg	0.02	Pass	0.042	Pass	0.026	Pass
Dose for first 30 days not to exceed			60 mg	0.02	Pass	0.042	Pass	0.026	Pass
Lifetime dose not to exceed****			2500 mg	0.02	Pass	0.042	Pass	0.026	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.1 mg/day	8.0×10^{-07}	Pass	1.7×10^{-06}	Pass	1.0×10^{-06}	Pass
Blank Control – No EO exposure			N/A	0.005	N/A				
				ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail
Dose for first 24 hours not to exceed		ECH	9 mg	0.041	Pass	0.015	Pass	0.01	Pass
Dose for first 30 days not to exceed			60 mg	0.041	Pass	0.015	Pass	0.01	Pass
Lifetime dose not to exceed****			10,000 mg	0.041	Pass	0.015	Pass	0.01	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.4 mg/day	1.7×10^{-06}	Pass	6.2×10^{-07}	Pass	4.0×10^{-07}	Pass
Blank Control – No EO exposure			N/A	0.001	N/A				

*Reference Attachment 7. **Reference Attachment 9. ***Reference Attachment 11.

****Medtronic Chemical Technologies exhaustively extracts until the last residual extraction result is less than 10% of the first extraction result (taken at 24 hours), which represents the lifetime dose. Based on the results above, the reported 30 day dose is the same as the lifetime dose.

Table 45: Limited Exposure EO and ECH Residual Results for the 6996SQ-85 Lead (Simulated Use)

Residual Type	EO Residual Specification	Extraction Temperature	Components Extracted (pooled together)	Acceptance Criteria	*1X Results – 4 hrs. forced heat		**3X Results – 4, 8, 8 hrs. forced heat		***4X Results – 4,8,8,8 hrs. forced heat	
					Result (mg)	Pass /Fail	Result (mg)	Pass /Fail	Result (mg)	Pass /Fail
EO	Dose for first 24 hours not to exceed (average daily dose)	25°C	slitters	4 mg	0.007	Pass	0.005	Pass	0.005	Pass
	Blank Control – No EO exposure				0.005	Pass				
	Dose for first 24 hours not to exceed (average daily dose)	37°C	stylet assemblies and stylet guides		0.005	Pass	0.005	Pass	0.005	Pass
	Blank Control – No EO exposure			N/A	0.005	Pass				
ECH	Dose for first 24 hours not to exceed (average daily dose)	25°C	slitters	9 mg	0.005	Pass	0.005	Pass	0.005	Pass
	Blank Control – No EO exposure			N/A	0.005	Pass				
	Dose for first 24 hours not to exceed (average daily dose)	37°C	stylet assemblies and stylet guides	9 mg	0.005	Pass	0.005	Pass	0.005	Pass
	Blank Control – No EO exposure			N/A	0.005	Pass				

*Reference Attachment 7. **Reference Attachment 9. ***Reference Attachment 11.

Table 46: 6996SQ-85 Individual Component Surface Areas

Lead Components	Surface Area	Quantity	Total Surface Area
Lead and anchoring sleeve – 502345307	73.12	1	73.12
Slitter – 103343007	15.15	2	30.3
Stylet Assembly – 404028002	12.31	1	12.31
Stylet Guide - 105125001	2.59	1	2.59

Table 47: EO Tolerable Contact Limit for the 6996SQ-85 Leads

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (µg/cm^2)	$m_{dev, BSC}$ = *A* x TCL (µg)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev, BSC}$ = *A* x TCL (mg)	Result $m_{dev, BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	73.12*	10	731.2*	≤ 0.7312	0.02	Pass	8
	3x						0.01	Pass	10
	4x						0.03	Pass	12
Limited**	1x	25°C	30.3**		303**	≤ 0.303	0.007	Pass	7
	3x						0.005	Pass	9
	4x						0.005	Pass	11
Limited***	1x	37°C	14.9***		149***	≤ 0.149	0.005	Pass	7
	3x						0.005	Pass	9

	4x						0.005	Pass	11

*The "Lead" and "Anchoring Sleeve" were extracted using the exhaustive method at 37C. The surface calculation shown is derived by combining these component portions together; see Table 46.
**The "slitter" component portions were pooled together and extracted using the "simulated use" method at 25C for 1 hour. Therefore, the surface calculation shown is derived by combining these component portions together; see Table 46.
***The "stylet assembly" and "stylet guide" component portions were pooled together and extracted using the "simulated use" method at 37C for 1 hour. Therefore, the surface calculation shown is derived by combining these component portions together; see Table 46.

Table 48: ECH Tolerable Contact Limit for the 6996SQ-85 Leads

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (mg/cm^2)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev, BSC}$ = *A* x TCL (mg)	Result $m_{dev, BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	73.12*	5	≤ 365.6	0.005	Pass	8
	3x					0.006	Pass	10
	4x					0.006	Pass	12
Limited**	1x	25°C	30.3**		≤ 151.5	0.005	Pass	7
	3x					0.005	Pass	9
	4x					0.005	Pass	11
Limited***	1x	37°C	14.9***		≤ 74.5	0.005	Pass	7
	3x					0.005	Pass	9
	4x					0.005	Pass	11

*The "Lead" and "Anchoring Sleeve" were extracted using the exhaustive method at 37C. The surface calculation shown is derived by combining these component portions together; see Table 46.
**The "slitter" component portions were pooled together and extracted using the "simulated use" method at 25C for 1 hour. Therefore, the surface calculation shown is derived by combining these component portions together; see Table 46.
***The "stylet assembly" and "stylet guide" component portions were pooled together and extracted using the "simulated use" method at 37C for 1 hour. Therefore, the surface calculation shown is derived by combining these component portions together; see Table 46.

9.2 Low Voltage EO/ECH and TCL Results

9.2.1 5568-53 Lead Model – "Load Configuration A/A – Standard Lead Trays"

Table 49: Sterilant Residual EO and ECH Analysis Results for the Permanent Contact Portions of the 5568-53 model (Exhaustive Extraction) – Standard Lead Tray

Sterilant Residual Specification	Components Extracted (pooled together)	Residual Type	Acceptance Criteria	*1X Results – 2 hrs. forced heat		**3X Results – 2, 8, 8 hrs. forced heat		***4X Results – 2,8,8,8 hrs. forced heat	
				EO (mg)	Pass/Fail	EO (mg)	ECH (mg)	EO (mg)	ECH (mg)
Dose for first 24 hours not to exceed	Lead and Anchor Sleeve	EO	4 mg	0.09	Pass	0.02	Pass	0.02	Pass
Dose for first 30 days not to exceed			60 mg	0.1	Pass	0.02	Pass	0.02	Pass
Lifetime dose not to exceed****			2500 mg	0.1	Pass	0.02	Pass	0.02	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.1 mg/day	4.0×10^{-06}	Pass	7.2×10^{-07}	Pass	6.6×10^{-07}	Pass
Blank Control – No EO exposure			N/A	0.005	N/A				
				ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail
Dose for first 24 hours not to exceed		ECH	9 mg	0.02	Pass	0.009	Pass	0.001	Pass
Dose for first 30 days not to exceed			60 mg	0.02	Pass	0.009	Pass	0.001	Pass
Lifetime dose not to exceed****			10,000 mg	0.02	Pass	0.009	Pass	0.001	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.4 mg/day	9.8×10^{-07}	Pass	3.6×10^{-07}	Pass	4.3×10^{-08}	Pass
Blank Control – No EO exposure			N/A	0.001	N/A				

*Reference Attachment 13. **Reference Attachment 15. ***Reference Attachment 17.

****Medtronic Chemical Technologies exhaustively extracts until the last residual extraction result is less than 10% of the first extraction result (taken at 24 hours), which represents the lifetime dose. Based on the results above, the reported 30 day dose is the same as the lifetime dose.

Table 50: Limited Exposure EO and ECH Residual Results for the 5568-53 model (Simulated Use) – Standard Lead Tray

Residual Type	EO Residual Specification	Extraction Temperature	Components Extracted (pooled together)	Acceptance Criteria	*1X Results – 2 hrs. forced heat		**3X Results – 2,8,8 hrs. forced heat		***4X Results – 2,8,8,8 hrs. forced heat	
					Result (mg)	Pass /Fail	Result (mg)	Pass /Fail	Result (mg)	Pass /Fail
EO	Dose for first 24 hours not to exceed (average daily dose)	25°C	Pinch-on-Tool,Clip-2 and Stylet Guide	4 mg	0.04	Pass	0.02	Pass	0.02	Pass
	Blank Control – No EO exposure			N/A	0.005	NA				
	Dose for first 24 hours not to exceed (average daily dose)	37°C	Stylet Assembly, J-Stylet, Vein Lifter	4 mg	0.11	Pass	0.02	Pass	0.02	Pass
	Blank Control – No EO exposure			N/A	0.01	NA				
ECH	Dose for first 24 hours not to exceed (average daily dose)	25°C	Pinch-on-Tool,Clip-2 and Stylet Guide	9 mg	0.005	Pass	0.01	Pass	0.01	Pass
	Blank Control – No EO exposure			N/A	0.005	NA				
	Dose for first 24 hours not to exceed (average daily dose)	37°C	Stylet Assembly, J-Stylet, Vein Lifter	9 mg	0.01	Pass	0.01	Pass	0.01	Pass
	Blank Control – No EO exposure			N/A	0.01	NA				

*Reference Attachment 13. **Reference Attachment 15. ***Reference Attachment 17

Table 51: 5568-53 Individual Component Surface Areas

Components	Surface Area (cm^2)	Quantity	Total Surface Area (cm^2)
Lead and Anchoring Sleeve – 502105902 (Standard Lead Tray)	42.76	1	42.76
Vein Lifter – 103548001	11.48	1	11.48
J-Stylet – 211310002	8.48	1	8.48
Stylet Assembly – 136529008	8.93	3	26.79
Pinch-On-Tool – 800471001	28.37	2	56.74
Clip-2 - 119478001	4.06	2	8.12
Stylet Guide - 105115001	2.58	1	2.58

Table 52: EO Tolerable Contact Limit for the 5568-53 Model – Standard Lead Tray

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL ($\mu g/cm^2$)	$m_{dev, BSC}$ = *A* x TCL (µg)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev, BSC}$ = *A* x TCL (mg)	Result $m_{dev, BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	42.76*	10	427.6	≤ 0.4276	0.08	Pass	14
	3x						0.02	Pass	16
	4x						0.03	Pass	18
Limited *	1x	25°C	67.44***		674.4	≤ 0.6744	0.04	Pass	13
	3x						0.02	Pass	15
	4x						0.02	Pass	17
Limited *	1x	37°C	46.75**		467.5	≤ 0.4675	0.11	Pass	13
	3x						0.02	Pass	15
	4x						0.02	Pass	17

*****The "Lead and anchoring sleeve"" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these component portions together; see Table 51.

******The "Stylets" and "Veinlifter" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 51.

*******The "Pinch-on-Tool", "stylet guide" and "clip-2" were extracted using the exhaustive method at 25°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 51.

Table 53: ECH Tolerable Contact Limit for the 5568-53 Model – Standard Lead Tray

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (mg/cm^2)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev, BSC}$ = *A* x TCL (mg)	Result $m_{dev, BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	42.76*	5	≤ 213.8	0.02	Pass	14
	3x					0.006	Pass	16
	4x					0.005	Pass	18
Limited *	1x	25°C	67.44***		≤ 337.2	0.005	Pass	13
	3x					0.01	Pass	15
	4x					0.01	Pass	17
Limited *	1x	37°C	46.75**		≤ 233.75	0.01	Pass	13
	3x					0.01	Pass	15
	4x					0.01	Pass	17

*****The "Lead and anchoring sleeve"" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these component portions together; see Table 51.

******The "Stylets" and "Veinlifter" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 51.

*******The "Pinch-on-Tool", "stylet guide" and "clip-2" were extracted using the exhaustive method at 25°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 51.

9.2.2 5568-53 Lead Model – "Load Configuration I/I – DELP Trays"

Table 54: Sterilant Residual EO and ECH Analysis Results for the Permanent Contact Portions of the 5568-53 model (Exhaustive Extraction) – DELP Tray

Sterilant Residual Specification	Components Extracted (pooled together)	Residual Type	Acceptance Criteria	*1X Results – 2 hrs. forced heat		**3X Results – 2, 8, 8 hrs. forced heat		***4X Results – 2,8,8,8 hrs. forced heat	
				EO (mg)	Pass/Fail	EO (mg)	Pass/Fail	EO (mg)	Pass/Fail
Dose for first 24 hours not to exceed	Lead and Anchor Sleeve	EO	4 mg	0.14	Pass	0.02	Pass	0.02	Pass
Dose for first 30 days not to exceed			60 mg	0.16	Pass	0.03	Pass	0.03	Pass
Lifetime dose not to exceed****			2500 mg	0.16	Pass	0.03	Pass	0.03	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.1 mg/day	6.5×10^{-06}	Pass	1.0×10^{-06}	Pass	1.2×10^{-06}	Pass
Blank Control – No EO exposure			N/A	0.005	N/A				
				ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail
Dose for first 24 hours not to exceed		ECH	9 mg	0.02	Pass	0.006	Pass	0.005	Pass
Dose for first 30 days not to exceed			60 mg	0.02	Pass	0.006	Pass	0.005	Pass
Lifetime dose not to exceed****			10,000 mg	0.02	Pass	0.006	Pass	0.005	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.4 mg/day	8.8×10^{-07}	Pass	2.4×10^{-07}	Pass	2.0×10^{-07}	Pass
Blank Control – No EO exposure			N/A	0.001	N/A				

*Reference Attachment 19. **Reference Attachment 21. ***Reference Attachment 23.

****Medtronic Chemical Technologies exhaustively extracts until the last residual extraction result is less than 10% of the first extraction result (taken at 24 hours), which represents the lifetime dose. Based on the results above, the reported 30 day dose is the same as the lifetime dose.

Table 55: Limited Exposure EO and ECH Residual Results for the 5568-53 model (Simulated Use) – DELP Tray

Residual Type	EO Residual Specification	Extraction Temperature	Components Extracted (pooled together)	Acceptance Criteria	*1X Results – 2 hrs. forced heat		**3X Results – 2,8,8 hrs. forced heat		***4X Results – 2,8,8,8 hrs. forced heat	
					Result (mg)	Pass /Fail	Result (mg)	Pass /Fail	Result (mg)	Pass /Fail
EO	Dose for first 24 hours not to exceed (average daily dose)	25°C	Pinch-on-Tool,Clip-2 and Stylet Guide	4 mg	0.15	Pass	0.03	Pass	0.03	Pass
	Blank Control – No EO exposure			N/A	0.01	N/A				
	Dose for first 24 hours not to exceed (average daily dose)	37°C	Stylet Assembly, J-Stylet, Vein Lifter	4 mg	0.05	Pass	0.02	Pass	0.04	Pass
	Blank Control – No EO exposure			N/A	0.01	N/A				
ECH	Dose for first 24 hours not to exceed (average daily dose)	25°C	Pinch-on-Tool,Clip-2 and Stylet Guide	9 mg	0.01	Pass	0.01	Pass	0.01	Pass
	Blank Control – No EO exposure			N/A	0.01	N/A				
	Dose for first 24 hours not to exceed (average daily dose)	37°C	Stylet Assembly, J-Stylet, Vein Lifter	9 mg	0.005	Pass	0.01	Pass	0.01	Pass
	Blank Control – No EO exposure			N/A	0.01	N/A				

*Reference Attachment 19. **Reference Attachment 21. ***Reference Attachment 23.

Table 56: 5568-53 Individual Component Surface Areas

Components	Surface Area (cm^2)	Quantity	Total Surface Area (cm^2)
Lead and Anchoring Sleeve – 502105916 (DELP)	42.76	1	42.76
Vein Lifter – 103548001	11.48	1	11.48
J-Stylet – 211310002	8.48	1	8.48
Stylet Assembly – 136529008	8.93	3	26.79
Pinch-On-Tool – 800471001	28.37	2	56.74
Clip-2 - 119478001	4.06	2	8.12
Stylet Guide - 105115001	2.58	1	2.58

Table 57: EO Tolerable Contact Limit for the 5568-53 Model – DELP Tray

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL ($\mu g/cm^2$)	$m_{dev,BSC}$ = *A* x TCL (µg)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,BSC}$ = *A* x TCL (mg)	Result $m_{dev,BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	42.76*	10	427.6	≤ 0.4276	0.08	Pass	20
	3x						0.03	Pass	22
	4x						0.02	Pass	24
Limited ***	1x	25°C	67.44***		674.4	≤ 0.6744	0.15	Pass	19
	3x						0.03	Pass	21
	4x						0.03	Pass	23
Limited **	1x	37°C	46.75**		467.5	≤ 0.4675	0.05	Pass	19
	3x						0.02	Pass	21
	4x						0.04	Pass	23

*****The "Lead and anchoring sleeve"" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these component portions together; see Table 56.

******The "Stylet Assembly", "J-Stylet" and " Vein Lifter" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 56.

*******The "Pinch-on-Tool","Clip-2" and "Stylet Guide" were extracted using the exhaustive method at 25°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 56.

Table 58: ECH Tolerable Contact Limit for the 5568-53 Model – DELP Tray

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (mg/cm^2)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,BSC}$ = *A* x TCL (mg)	Result $m_{dev,BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	42.76*	5	≤ 213.8	0.02	Pass	20
	3x					0.006	Pass	22
	4x					0.005	Pass	24
Limited ***	1x	25°C	67.44***		≤ 337.2	0.01	Pass	19
	3x					0.01	Pass	21
	4x					0.01	Pass	23
Limited **	1x	37°C	46.75**		≤ 233.75	0.005	Pass	19
	3x					0.01	Pass	21
	4x					0.01	Pass	23

*****The "Lead and anchoring sleeve"" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these component portions together; see Table 56.

******The "Stylet Assembly", "J-Stylet" and " Vein Lifter" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 56.

*******The "Pinch-on-Tool","Clip-2" and "Stylet Guide" were extracted using the exhaustive method at 25°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 56

9.2.3 5038-65 Lead Model – "Load Configuration A/A – Standard Lead Trays"

Table 59: Sterilant Residual EO and ECH Analysis Results for the Permanent Contact Portions of the 5038-65 model (Exhaustive Extraction) – Standard Lead Tray

Sterilant Residual Specification	Components Extracted (pooled together)	Residual Type	Acceptance Criteria	*1X Results – 4 hrs. forced heat		**3X Results – 4, 8, 8 hrs. forced heat		***4X Results – 4,8,8,8 hrs. forced heat	
				EO (mg)	Pass/Fail	EO (mg)	Pass/Fail	EO (mg)	Pass/Fail
Dose for first 24 hours not to exceed	Lead and Anchor Sleeve	EO	4 mg	0.13	Pass	0.04	Pass	0.03	Pass
Dose for first 30 days not to exceed			60 mg	0.14	Pass	0.06	Pass	0.06	Pass
Lifetime dose not to exceed****			2500 mg	0.14	Pass	0.06	Pass	0.06	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.1 mg/day	5.6×10^{-06}	Pass	2.5×10^{-06}	Pass	2.3×10^{-06}	Pass
*****Blank Control – No EO exposure			N/A			0.005	N/A		
				ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail
Dose for first 24 hours not to exceed		ECH	9 mg	0.01	Pass	0.02	Pass	0.006	Pass
Dose for first 30 days not to exceed			60 mg	0.03	Pass	0.03	Pass	0.006	Pass
Lifetime dose not to exceed****			10,000 mg	0.03	Pass	0.03	Pass	0.006	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.4 mg/day	1.2×10^{-06}	Pass	1.1×10^{-06}	Pass	2.5×10^{-07}	Pass
*****Blank Control – No EO exposure			N/A			0.001	N/A		

*Reference DL991732 (ref. section 4.0). Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The EO results in the Table 59 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 5038 is compliant to ISO 10993-7:2008/AC:2009.
**Reference Attachment 25. ***Reference Attachment 27.
****Medtronic Chemical Technologies exhaustively extracts until the last residual extraction result is less than 10% of the first extraction result (taken at 24 hours), which represents the lifetime dose. Based on the results above, the reported 30 day dose is the same as the lifetime dose.
*****Blank sample was tested with the submission of the 3X samples.

Table 60: Limited Exposure EO and ECH Residual Results for the 5038-65 model (Simulated Use) – Standard Lead Tray

Residual Type	EO Residual Specification	Extraction Temperature	Components Extracted (pooled together)	Acceptance Criteria	*1X Results – 4 hrs. forced heat		**3X Results – 4,8,8 hrs. forced heat		***4X Results – 4,8,8,8 hrs. forced heat	
					Result (mg)	Pass /Fail	Result (mg)	Pass /Fail	Result (mg)	Pass /Fail
EO	Dose for first 24 hours not to exceed (average daily dose)	25°C	Stylet Guide	4 mg	0.03	Pass	0.005	Pass	0.005	Pass
	****Blank Control – No EO exposure			N/A			0.005	NA		
	Dose for first 24 hours not to exceed (average daily dose)	37°C	Stylet Assembly and Vein Lifter	4 mg			0.02	Pass	0.02	Pass
	****Blank Control – No EO exposure			N/A			0.01	NA		
ECH	Dose for first 24 hours not to exceed (average daily dose)	25°C	Stylet Guide	9 mg	0.004	Pass	0.005	Pass	0.005	Pass
	****Blank Control – No EO exposure			N/A			0.005	NA		
	Dose for first 24 hours not to exceed (average daily dose)	37°C	Stylet Assembly and Vein Lifter	9 mg			0.005	Pass	0.01	Pass
	****Blank Control – No EO exposure			N/A			0.01	NA		

*Reference DL991732 (ref. section 4.0). Simulated extraction was performed at 37°C for 1 hour on all limited use components. All components were pooled. Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The EO and ECH results in the Table 60 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 5038 is compliant to ISO 10993-7:2008/AC:2009.
**Reference Attachment 25. ***Reference Attachment 27.
****Blank sample was tested with the submission of the 3X samples.

Table 61: 5038-65 Individual Component Surface Areas

Components	Surface Area (cm^2)	Quantity	Total Surface Area (cm^2)
Lead and anchoring sleeve – 502308509 (standard lead tray)	64.28	1	64.28
Vein Lifter – 103548001	11.48	1	11.48
Stylet Assembly - 136528008	10.81	1	10.81
Stylet Assembly - 136529002	10.42	1	10.42
Stylet Assembly - 404028004	10.02	1	10.02
Stylet Guide – 105115001	2.58	1	2.58

Table 62: EO Tolerable Contact Limit for the 5038-65 Model – Standard Lead Tray

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL ($\mu g/cm^2$)	$m_{dev,BSC}$ = *A* x TCL (µg)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,BSC}$ = *A* x TCL (mg)	Result $m_{dev,BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	64.28*	10	642.8	≤ 0.6428	0.13****	Pass	****
	3x						0.02	Pass	26
	4x						0.04	Pass	28
Limited ***	1x	25°C	2.58**		25.8	≤ 0.0258	0.03****	Pass	****
	3x						0.005	Pass	25
	4x						0.005	Pass	27
Limited **	1x	37°C	42.73***		427.3	≤ 0.4273	0.03****	Pass	****
	3x						0.02	Pass	25
	4x						0.02	Pass	27

*****The "Lead and anchoring sleeve"" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these component portions together; see Table 61.

******The "Stylet Assemblies" and "Vein Lifter" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 61.

*******The "Stylet Guide" was extracted using the exhaustive method at 25°C for 1 hour. See Table 61 for surface area.

****Reference DL991732 (ref. section 4.0). Simulated extraction was performed at 37°C for 1 hour on all limited use components. All components were pooled. Acceptance criteria for pooled components is ≤ 0.4531 mg. Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The EO TCL results in the Table 62 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 5038 is compliant to ISO 10993-7:2008/AC:2009.

Table 63: ECH Tolerable Contact Limit for the 5038-65 Model – Standard Lead Tray

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (mg/cm^2)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,BSC}$ = *A* x TCL (mg)	Result $m_{dev,BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	64.28*	5	≤ 321.4	0.01****	Pass	****
	3x					0.01	Pass	26
	4x					0.01	Pass	28
Limited ***	1x	25°C	2.58**		≤ 12.9	0.004****	Pass	****
	3x					0.005	Pass	25
	4x					0.005	Pass	27
Limited **	1x	37°C	42.73***		≤ 213.65	0.004****	Pass	****
	3x					0.005	Pass	25
	4x					0.01	Pass	27

*****The "Lead and anchoring sleeve"" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these component portions together; see Table 61.

******The "Stylet Assemblies" and "Vein Lifter" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 61.

*******The "Stylet Guide" was extracted using the exhaustive method at 25°C for 1 hour. See Table 61 for surface area.

****Reference DL991732 (ref. section 4.0). Simulated extraction was performed at 37°C for 1 hour on all limited use components. All components were pooled. Acceptance criteria for pooled components is ≥ 226.55 mg. Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The ECH TCL results in the Table 63 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 5038 is compliant to ISO 10993-7:2008/AC:2009.

9.2.4 5038-65 Lead Model "Load Configuration I/I – DELP Trays"

Table 64: Sterilant Residual EO and ECH Analysis Results for the Permanent Contact Portions of the 5038-65 model (Exhaustive Extraction) – DELP Tray

Sterilant Residual Specification	Components Extracted (pooled together)	Residual Type	Acceptance Criteria	*1X Results – 4 hrs. forced heat		**3X Results – 4, 8, 8 hrs. forced heat		***4X Results – 4,8,8,8 hrs. forced heat	
				EO (mg)	Pass/Fail	EO (mg)	Pass/Fail	EO (mg)	Pass/Fail
Dose for first 24 hours not to exceed	Lead and Anchor Sleeve	EO	4 mg	0.09	Pass	0.06	Pass	0.05	Pass
Dose for first 30 days not to exceed			60 mg	0.13	Pass	0.08	Pass	0.07	Pass
Lifetime dose not to exceed****			2500 mg	0.13	Pass	0.08	Pass	0.07	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2008 (ref. section 4.0)]}			0.1 mg/day	5.2×10^{-06}	Pass	3.3×10^{-06}	Pass	2.8×10^{-06}	Pass
Blank Control – No EO exposure			N/A	0.005	N/A				
				ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail
Dose for first 24 hours not to exceed		ECH	9 mg	0.008	Pass	0.02	Pass	0.02	Pass
Dose for first 30 days not to exceed			60 mg	0.008	Pass	0.03	Pass	0.02	Pass
Lifetime dose not to exceed****			10,000 mg	0.008	Pass	0.03	Pass	0.02	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/ AC:2008 (ref. section 4.0)]}			0.4 mg/day	3.2×10^{-07}	Pass	1.2×10^{-06}	Pass	8.2×10^{-07}	Pass
Blank Control – No EO exposure			N/A	0.001	N/A				

*Reference Attachment 29. **Reference Attachment 31. ***Reference Attachment 33.
****Medtronic Chemical Technologies exhaustively extracts until the last residual extraction result is less than 10% of the first extraction result (taken at 24 hours), which represents the lifetime dose. Based on the results above, the reported 30 day dose is the same as the lifetime dose.

Table 65: Limited Exposure EO and ECH Residual Results for the 5038-65 model (Simulated Use) – DELP Tray

Residual Type	EO Residual Specification	Extraction Temperature	Components Extracted (pooled together)	Acceptance Criteria	*1X Results – 4 hrs. forced heat		**3X Results – 4,8,8 hrs. forced heat		***4X Results – 4,8,8,8 hrs. forced heat	
					Result (mg)	Pass /Fail	Result (mg)	Pass /Fail	Result (mg)	Pass /Fail
EO	Dose for first 24 hours not to exceed (average daily dose)	25°C	Stylet Guide	4 mg	0.005	Pass	0.005	Pass	0.005	Pass
	Blank Control – No EO exposure			N/A	0.005	NA				
	Dose for first 24 hours not to exceed (average daily dose)	37°C	Stylet Assembly, and Vein Lifter	4 mg	0.05	Pass	0.03	Pass	0.02	Pass
	Blank Control – No EO exposure			N/A	0.01	NA				
ECH	Dose for first 24 hours not to exceed (average daily dose)	25°C	Stylet Guide	9 mg	0.005	Pass	0.005	Pass	0.005	Pass
	Blank Control – No EO exposure			N/A	0.005	NA				
	Dose for first 24 hours not to exceed (average daily dose)	37°C	Stylet Assembly, and Vein Lifter	9 mg	0.01	Pass	0.01	Pass	0.01	Pass
	Blank Control – No EO exposure			N/A	0.01	NA				

*Reference Attachment 29. **Reference Attachment 31. ***Reference Attachment 33.

Table 66: 5038-65 Individual Component Surface Areas

Components	Surface Area (cm^2)	Quantity	Total Surface Area (cm^2)
Lead and anchoring sleeve – 502308509 (standard lead tray)	64.28	1	64.28
Vein Lifter – 103548001	11.48	1	11.48
Stylet Assembly - 136528008	10.81	1	10.81
Stylet Assembly - 136529002	10.42	1	10.42
Stylet Assembly - 404028004	10.02	1	10.02
Stylet Guide – 105115001	2.58	1	2.58

Table 67: EO Tolerable Contact Limit for the 5038-65 Model – DELP Tray

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL ($\mu g/cm^2$)	$m_{dev,BSC}$ = *A* x TCL (µg)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,BSC}$ = *A* x TCL (mg)	Result $m_{dev,BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	64.28*	10	642.8	≤ 0.6428	0.2	Pass	30
	3x						0.06	Pass	32
	4x						0.04	Pass	34
Limited ***	1x	25°C	2.58**		25.8	≤ 0.0258	0.005	Pass	29
	3x						0.005	Pass	31
	4x						0.005	Pass	33
Limited **	1x	37°C	42.73***		427.3	≤ 0.4273	0.06	Pass	29
	3x						0.03	Pass	31
	4x						0.02	Pass	33

*****The "Lead and anchoring sleeve"" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these component portions together; see Table 66.

******The "Stylet Assemblies" and "Vein Lifter" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 66.

*******The "Stylet Guide" was extracted using the exhaustive method at 25°C for 1 hour.

Table 68: ECH Tolerable Contact Limit for the 5038-65 Model – DELP Tray

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (mg/cm^2)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,BSC}$ = *A* x TCL (mg)	Result $m_{dev,BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	64.28*	5	≤ 321.4	0.006	Pass	30
	3x					0.01	Pass	32
	4x					0.01	Pass	34
Limited ***	1x	25°C	2.58**		≤ 12.9	0.005	Pass	29
	3x					0.005	Pass	31
	4x					0.005	Pass	33
Limited **	1x	37°C	42.73***		≤ 213.65	0.01	Pass	29
	3x					0.01	Pass	31
	4x					0.01	Pass	33

*****The "Lead and anchoring sleeve"" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these component portions together; see Table 66.

******The "Stylet Assemblies" and "Vein Lifter" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 66.

*******The "Stylet Guide" was extracted using the exhaustive method at 25°C for 1 hour.

9.2.5 4193-103 Lead Model "Load Configuration I/I – DELP Trays"

Table 69: Sterilant Residual EO and ECH Analysis Results for the Permanent Contact Portions of the 4193-103 Lead (Exhaustive Extraction)

Sterilant Residual Specification	Components Extracted (pooled together)	Residual Type	Acceptance Criteria	*1X Results – 4 hrs. forced heat		**3X Results – 4,8,8 hrs. forced heat	
				EO (mg)	Pass/Fail	EO (mg)	Pass/Fail
Dose for first 24 hours not to exceed	*Lead and Anchor Sleeve*	EO	4 mg	0.05	Pass	0.014	Pass
Dose for first 30 days not to exceed			60 mg	0.07	Pass	0.014	Pass
Lifetime dose not to exceed***			2500 mg	0.07	Pass	0.014	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.1 mg/day	2.8×10^{-06}	Pass	5.7×10^{-07}	Pass
****Blank Control – No EO exposure			N/A			0.005	N/A
				ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail
Dose for first 24 hours not to exceed		ECH	9 mg	0.0007	Pass	0.001	Pass
Dose for first 30 days not to exceed			60 mg	0.0007	Pass	0.001	Pass
Lifetime dose not to exceed***			10,000 mg	0.0007	Pass	0.001	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.4 mg/day	2.7×10^{-07}	Pass	4.3×10^{-08}	Pass
****Blank Control – No EO exposure			N/A			0.001	N/A

*Reference Chemical Technologies Lims # 20911006 (ref. section 4.0). Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The EO results in the Table 69 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 4193 is compliant to ISO 10993-7:2008/AC:2009.

**Reference Attachment 35.

***Medtronic Chemical Technologies exhaustively extracts until the last residual extraction result is less than 10% of the first extraction result (taken at 24 hours), which represents the lifetime dose. Based on the results above, the reported 30 day dose is the same as the lifetime dose.

****Blank sample was tested with the submission of the 3X samples.

Table 70: Limited Exposure EO and ECH Residual Results for the 4193-103 Lead (Simulated Use)

Residual Type	EO Residual Specification	Extraction Temperature	Components Extracted (pooled together)	Acceptance Criteria	*1X Results – 4 hrs. forced heat		**3X Results – 4,8,8 hrs. forced heat	
					Result (mg)	Pass /Fail	Result (mg)	Pass /Fail
EO	Dose for first 24 hours not to exceed (average daily dose)	25°C	Tool Back loading/Front loading and Steering Handle	4 mg	0.172	Pass	0.03	Pass
	***Blank Control – No EO exposure			N/A			0.005	NA
	Dose for first 24 hours not to exceed (average daily dose)	37°C	Stylet Assembly and Guidewire Clip	4 mg			0.03	Pass
	***Blank Control – No EO exposure			N/A			0.01	NA
ECH	Dose for first 24 hours not to exceed (average daily dose)	25°C	Tool Back loading/Front loading and Steering Handle	9 mg	0.004	Pass	0.005	Pass
	***Blank Control – No EO exposure			N/A			0.005	NA
	Dose for first 24 hours not to exceed (average daily dose)	37°C	Stylet Assembly and Guidewire Clip	9 mg			0.01	Pass
	***Blank Control – No EO exposure			N/A			0.01	NA

* Reference Chemical Technologies Lims # 20911006 (ref. section 4.0). Simulated extraction was performed at 37°C for 1 hour on all limited use components. All limited components were pooled. Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The EO and ECH results in the Table 70 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 4193 is compliant to ISO 10993-7:2008/AC:2009.
**Reference Attachment 35.
***Blank sample was tested with the submission of the 3X samples.

Table 71: 4193-103 Individual Component Surface Areas

Lead Components	Surface Area (cm^2)	Quantity	Total Surface Area (cm^2)
Lead and Anchoring Sleeve - 502687910	61.91	1	61.91
Stylet Assembly – 411059004	15.07	1	15.07
Stylet Assembly – 411058004	13.65	1	13.65
Stylet Assembly - 411057004	15.05	2	30.1
Tool Back loading/Front loading - 184723001	13.13	1	13.13
Steering Handle - 177985001	35.04	1	35.04
Guidewire Clip - 177984001	24.36	1	24.36

Table 72: EO Tolerable Contact Limit for the 4193-103 Lead

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL ($\mu g/cm^2$)	$m_{dev, BSC}$ = *A* x TCL (µg)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev, BSC}$ = *A* x TCL (mg)	Result $m_{dev, BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	61.91*	10	619.1	≤ 0.6191	0.07****	Pass	****
	3x						0.009	Pass	36
Limited**	1x	25°C	48.17**		481.7	≤ 0.4817	0.17****	Pass	****
	3x						0.03	Pass	35
Limited***	1x	37°C	83.18***		831.8	≤ 0.8318	0.17****	Pass	****
	3x						0.03	Pass	35

**The "Lead and Anchoring Sleeve" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these component portions together; see Table 71.
**The "Tool Back loading/Front loading" and "Steering Handle" component portions were pooled together and extracted using the "simulated use" method at 25°C for 1 hour. Therefore, the surface calculation shown is derived by combining these component portions together; see Table 71.
***The Stylet Assemblies and "Guide Wire Clip" (see deviations section 10.0) were extracted using the simulated method at 37°C for 1 hour. Therefore, the surface calculation shown is derived by combining these component portions together; see Table 71.
****Reference Chemical Technologies Lims # 20911006 (ref. section 4.0). Simulated extraction was performed at 37°C for 1 hour on all limited use components. All limited contact components were pooled. Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The EO TCL results in the Table 72 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 4193 is compliant to ISO 10993-7:2008/AC:2009.

Table 73: ECH Tolerable Contact Limit for the 4193-103 Lead

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (mg/cm^2)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev, BSC}$ = *A* x TCL (mg)	Result $m_{dev, BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	61.91*	5	≤ 309.55	0.007****	Pass	****
	3x					0.005	Pass	36
Limited**	1x	25°C	48.17**		≤ 240.85	0.004****	Pass	****
	3x					0.005	Pass	35
Limited***	1x	37°C	83.18***		≤ 415.9	0.004****	Pass	****
	3x					0.01	Pass	35

**The "Lead and Anchoring Sleeve" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these component portions together; see Table 71.
** The "Tool Back loading/Front loading" and "Steering Handle" component portions were pooled together and extracted using the "simulated use" method at 25°C for 1 hour. Therefore, the surface calculation shown is derived by combining these component portions together; see Table 71.
***The Stylet Assemblies and "Guide Wire Clip" (see deviations section 10.0) were extracted using the simulated method at 37°C for 1 hour. Therefore, the surface calculation shown is derived by combining these component portions together; see Table 71.
****Reference Chemical Technologies Lims # 20911006 (ref. section 4.0). Simulated extraction was performed at 37°C for 1 hour on all limited use components. All limited contact components were pooled. Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The ECH results in the Table 73 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 4193 is compliant to ISO 10993-7:2008/AC:2009.

9.2.6 4194-103 Lead Model "Load Configuration I/I – DELP Trays"

Table 74: Sterilant Residual EO and ECH Analysis Results for the Permanent Contact Portions of the 4194-103 Lead (Exhaustive Extraction)

Sterilant Residual Specification	Components Extracted (pooled together)	Residual Type	Acceptance Criteria	*1X Results – 4 hrs. forced heat		**3X Results – 4,8,8 hrs. forced heat	
				EO (mg)	Pass/Fail	EO (mg)	Pass/Fail
Dose for first 24 hours not to exceed	*Lead and Anchor Sleeve*	EO	4 mg	0.37	Pass	0.06	Pass
Dose for first 30 days not to exceed			60 mg	0.13	Pass	0.07	Pass
Lifetime dose not to exceed***			2500 mg	0.13	Pass	0.07	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.1 mg/day	5.2×10^{-06}	Pass	3.0×10^{-06}	Pass
****Blank Control – No EO exposure			N/A			0.005	N/A
				ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail
Dose for first 24 hours not to exceed		ECH	9 mg	0.007	Pass	0.001	Pass
Dose for first 30 days not to exceed			60 mg	0.004	Pass	0.001	Pass
Lifetime dose not to exceed***			10,000 mg	0.004	Pass	0.001	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.4 mg/day	1.5×10^{-07}	Pass	4.3×10^{-08}	Pass
****Blank Control – No EO exposure			N/A			0.001	N/A

*Reference Chemical Technologies Lims # 20911006 (ref. section 4.0). Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The EO results in the Table 74 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 4194 is compliant to ISO 10993-7:2008/AC:2009.

**Reference Attachment 37.

***Medtronic Chemical Technologies exhaustively extracts until the last residual extraction result is less than 10% of the first extraction result (taken at 24 hours), which represents the lifetime dose. Based on the results above, the reported 30 day dose is the same as the lifetime dose.

****Blank sample was tested with the submission of the 3X samples.

Table 75: Limited Exposure EO and ECH Residual Results for the 4194-103 Lead (Simulated Use)

Residual Type	EO Residual Specification	Extraction Temperature	Components Extracted (pooled together)	Acceptance Criteria	*1X Results – 4 hrs. forced heat		**3X Results – 4,8,8 hrs. forced heat	
					Result (mg)	Pass /Fail	Result (mg)	Pass /Fail
EO	Dose for first 24 hours not to exceed (average daily dose)	25°C	Tool Back loading/Front loading and Steering Handle	4 mg	0.163	Pass	0.01	Pass
	Blank Control – No EO exposure			N/A			0.005	NA
	Dose for first 24 hours not to exceed (average daily dose)	37°C	Stylet Assembly and Guidewire Clip	4 mg			0.05	Pass
	Blank Control – No EO exposure			N/A			0.01	NA
ECH	Dose for first 24 hours not to exceed (average daily dose)	25°C	Tool Back loading/Front loading and Steering Handle	9 mg	0.004	Pass	0.005	Pass
	Blank Control – No EO exposure			N/A			0.005	NA
	Dose for first 24 hours not to exceed (average daily dose)	37°C	Stylet Assembly and Guidewire Clip	9 mg			0.01	Pass
	***Blank Control – No EO exposure			N/A			0.01	NA

* Reference Chemical Technologies Lims # 20911006 (ref. section 4.0). Simulated extraction was performed at 37°C for 1 hour on all limited use components. All limited components were pooled. Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The EO and ECH results in the Table 75 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 4194 is compliant to ISO 10993-7:2008/AC:2009.
**Reference Attachment 37.
***Blank sample was tested with the submission of the 3X samples.

Table 76: 4194-103 Individual Component Surface Areas

Lead Components	Surface Area (cm^2)	Quantity	Total Surface Area (cm^2)
Lead and Anchoring Sleeve – 502906503	71.44	1	71.44
Stylet Assembly – 411059004	15.07	1	15.07
Stylet Assembly – 411058004	13.65	1	13.65
Stylet Assembly – 411057004	15.05	2	30.1
Tool Back loading/Front loading - 184723001	13.13	1	13.13
Steering Handle – 177985001	35.04	1	35.04
Guidewire Clip - 177984001	24.36	1	24.36

Table 77: EO Tolerable Contact Limit for the 4194-103 Lead

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL ($\mu g/cm^2$)	$m_{dev, BSC}$ = *A* x TCL (µg)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev, BSC}$ = *A* x TCL (mg)	Result $m_{dev, BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	71.44*	10	714.4	≤ 0.7144	0.13****	Pass	****
	3x						0.05	Pass	38
Limited**	1x	25°C	48.17**		481.7	≤ 0.4817	0.163****	Pass	****
	3x						0.01	Pass	37
Limited***	1x	37°C	83.18***		831.8	≤ 0.8318	0.163****	Pass	****
	3x						0.05	Pass	37

**The "Lead and Anchoring Sleeve" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these component portions together; see Table 76.
** The "Tool Back loading/Front loading" and "Steering Handle" component portions were pooled together and extracted using the "simulated use" method at 25°C for 1 hour. Therefore, the surface calculation shown is derived by combining these component portions together; see Table 76.
***The Stylet Assemblies and "Guide Wire Clip" (see deviations section 10.0) was extracted using the simulated method at 37°C for 1 hour. Therefore, the surface calculation shown is derived by combining these component portions together; see Table 76.
**** Reference Chemical Technologies Lims # 20911006 (ref. section 4.0). Simulated extraction was performed at 37°C for 1 hour on all limited use components. All limited contact components were pooled. Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The EO TCL results in the Table 77 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 4194 is compliant to ISO 10993-7:2008/AC:2009.

Table 78: ECH Tolerable Contact Limit for the 4194-103 Lead

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (mg/cm^2)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev, BSC}$ = *A* x TCL (mg)	Result $m_{dev, BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	71.44*	5	≤ 357.2	0.004****	Pass	****
	3x					0.005	Pass	38
Limited**	1x	25°C	48.17**		≤ 240.85	0.004****	Pass	****
	3x					0.005	Pass	37
Limited***	1x	37°C	83.18***		≤ 415.9	0.004****	Pass	****
	3x					0.01	Pass	37

**The "Lead and Anchoring Sleeve" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these component portions together; see Table 76.
** The "Tool Back loading/Front loading" and "Steering Handle" component portions were pooled together and extracted using the "simulated use" method at 25°C for 1 hour. Therefore, the surface calculation shown is derived by combining these component portions together; see Table 76.
***The Stylet Assemblies and "Guide Wire Clip" (see deviations section 10.0) was extracted using the simulated method at 37°C for 1 hour. Therefore, the surface calculation shown is derived by combining these component portions together; see Table 76.
**** Reference Chemical Technologies Lims # 20911006 (ref. section 4.0). Simulated extraction was performed at 37°C for 1 hour on all limited use components. All limited contact components were pooled. Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The ECH TCL results in the Table 78 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 4194 is compliant to ISO 10993-7:2008/AC:2009.

9.2.7 4073-65 Lead Model "Load Configuration I/I – DELP Trays"

Table 79: Sterilant Residual EO and ECH Analysis Results for the Permanent Contact Portions of the 4073-65 model (Exhaustive Extraction) – DELP Tray

Sterilant Residual Specification	Components Extracted (pooled together)	Residual Type	Acceptance Criteria	*1X Results – 2 hrs. forced heat		**3X Results – 2, 8, 8 hrs. forced heat		***4X Results – 2,8,8 hrs. forced heat	
				EO (mg)	Pass/Fail	EO (mg)	Pass/Fail	EO (mg)	Pass/Fail
Dose for first 24 hours not to exceed	Lead and Anchor Sleeve	EO	4 mg	0.02	Pass	0.01	Pass	0.01	Pass
Dose for first 30 days not to exceed			60 mg	0.02	Pass	0.01	Pass	0.01	Pass
Lifetime dose not to exceed****			2500 mg	0.02	Pass	0.01	Pass	0.01	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.1 mg/day	9.0×10^{-07}	Pass	3.9×10^{-07}	Pass	4.7×10^{-07}	Pass
Blank Control – No EO exposure			N/A	0.005	N/A				
				ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail
Dose for first 24 hours not to exceed		ECH	9 mg	0.001	Pass	0.001	Pass	0.001	Pass
Dose for first 30 days not to exceed			60 mg	0.001	Pass	0.001	Pass	0.001	Pass
Lifetime dose not to exceed****			10,000 mg	0.001	Pass	0.001	Pass	0.001	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.4 mg/day	4.3×10^{-08}	Pass	4.3×10^{-08}	Pass	4.3×10^{-08}	Pass
Blank Control – No EO exposure			N/A	0.001	N/A				

*Reference Attachment 39. **Reference Attachment 41. ***Reference Attachment 43.

****Medtronic Chemical Technologies exhaustively extracts until the last residual extraction result is less than 10% of the first extraction result (taken at 24 hours), which represents the lifetime dose. Based on the results above, the reported 30 day dose is the same as the lifetime dose.

Table 80: Limited Exposure EO and ECH Residual Results for the 4073-65 model (Simulated Use) – DELP Tray

Residual Type	EO Residual Specification	Extraction Temperature	Components Extracted (pooled together)	Acceptance Criteria	*1X Results – 2 hrs. forced heat		**3X Results – 2,8,8 hrs. forced heat		***4X Results – 2,8,8,8 hrs. forced heat	
					Result (mg)	Pass /Fail	Result (mg)	Pass /Fail	Result (mg)	Pass /Fail
EO	Dose for first 24 hours not to exceed (average daily dose)	25°C	Stylet Guide	4 mg	0.005	Pass	0.005	Pass	0.005	Pass
	Blank Control – No EO exposure			N/A	0.005	NA				
	Dose for first 24 hours not to exceed (average daily dose)	37°C	Stylet Assembly and Vein Lifter	4 mg	0.08	Pass	0.02	Pass	0.02	Pass
	Blank Control – No EO exposure			N/A	0.01	N/A				
ECH	Dose for first 24 hours not to exceed (average daily dose)	25°C	Stylet Guide	9 mg	0.005	Pass	0.005	Pass	0.005	Pass
	Blank Control – No EO exposure			N/A	0.005	Pass				
	Dose for first 24 hours not to exceed (average daily dose)	37°C	Stylet Assembly and Vein Lifter	9 mg	0.01	Pass	0.01	Pass	0.01	Pass
	Blank Control – No EO exposure			N/A	0.01	Pass				

*Reference Attachment 39. **Reference Attachment 41. ***Reference Attachment 43.

Table 81: 4073-65 Individual Component Surface Areas

Components	Surface Area (cm^2)	Quantity	Total Surface Area (cm^2)
Lead and anchoring sleeve – 502779506	64.28	1	64.28
Vein Lifter – 103548001	11.48	1	11.48
Stylet Assembly – 404028002	12.31	1	12.31
Stylet Assembly – 136529003	12.85	1	12.85
Stylet Assembly – 404553010	14.50	1	14.50
Stylet Guide - 105115001	2.58	1	2.58

Table 82: EO Tolerable Contact Limit for the 4073-65 Model – DELP Tray

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL ($\mu g/cm^2$)	$m_{dev,BSC}$ = *A* x TCL (µg)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,BSC}$ = *A* x TCL (mg)	Result $m_{dev,BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	65.4*	10	654	≤ 0.654	0.03	Pass	40
	3x						0.01	Pass	42
	4x						0.02	Pass	44
Limited ***	1x	25°C	2.58***		25.8	≤ 0.0258	0.005	Pass	39
	3x						0.005	Pass	41
	4x						0.005	Pass	43
Limited **	1x	37°C	51.14**		511.4	≤ 0.5114	0.08	Pass	39
	3x						0.02	Pass	41
	4x						0.02	Pass	43

*****The "Lead and anchoring sleeve"" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these component portions together; see Table 81.

******The "Stylet Assemblies" and "Vein Lifter" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 81.

*******The "Stylet Guide" was extracted using the exhaustive method at 25°C for 1 hour.

Table 83: ECH Tolerable Contact Limit for the 4073-65 Model – DELP Tray

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (mg/cm^2)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,BSC}$ = *A* x TCL (mg)	Result $m_{dev,BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	65.4*	5	≤ 327	0.005	Pass	40
	3x					0.005	Pass	42
	4x					0.005	Pass	44
Limited ***	1x	25°C	2.58***		≤ 12.9	0.005	Pass	39
	3x					0.005	Pass	41
	4x					0.005	Pass	43
Limited **	1x	37°C	51.14**		≤ 255.7	0.01	Pass	39
	3x					0.01	Pass	41
	4x					0.01	Pass	43

*****The "Lead and anchoring sleeve"" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these component portions together; see Table 81.

******The "Stylet Assemblies" and "Vein Lifter" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 81.

*******The "Stylet Guide" was extracted using the exhaustive method at 25°C for 1 hour.

9.2.8 4076-110 Lead Model "Load Configuration I/I – DELP Trays"

Table 84: Sterilant Residual EO and ECH Analysis Results for the Permanent Contact Portions of the 4076-110 model (Exhaustive Extraction) – DELP Tray

Sterilant Residual Specification	Components Extracted (pooled together)	Residual Type	Acceptance Criteria	*1X Results – 2 hrs. forced heat		**3X Results – 2, 8, 8 hrs. forced heat		***4X Results – 2,8,8,8 hrs. forced heat	
				EO (mg)	Pass/Fail	EO (mg)	Pass/Fail	EO (mg)	Pass/Fail
Dose for first 24 hours not to exceed	Lead and Anchor Sleeve	EO	4 mg	0.61	Pass	0.11	Pass	0.16	Pass
Dose for first 30 days not to exceed			60 mg	0.72	Pass	0.12	Pass	0.19	Pass
Lifetime dose not to exceed****			2500 mg	0.72	Pass	0.12	Pass	0.19	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.1 mg/day	0.0	Pass	4.99×10^{-06}	Pass	7.62×10^{-06}	Pass
Blank Control – No EO exposure			N/A	0.01	N/A				
				ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail
Dose for first 24 hours not to exceed		ECH	9 mg	2.11×10^{-02}	Pass	1.08×10^{-03}	Pass	1.08×10^{-03}	Pass
Dose for first 30 days not to exceed			60 mg	2.11×10^{-02}	Pass	1.08×10^{-03}	Pass	1.08×10^{-03}	Pass
Lifetime dose not to exceed****			10,000 mg	2.11×10^{-02}	Pass	1.08×10^{-03}	Pass	1.08×10^{-03}	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.4 mg/day	8.44×10^{-07}	Pass	4.32×10^{-08}	Pass	4.32×10^{-08}	Pass
Blank Control – No EO exposure			N/A	1.0×10^{-03}	N/A				

*Reference Attachment 83. **Reference Attachment 85. ***Reference Attachment 87.

****Medtronic Chemical Technologies exhaustively extracts until the last residual extraction result is less than 10% of the first extraction result (taken at 24 hours), which represents the lifetime dose. Based on the results above, the reported 30 day dose is the same as the lifetime dose.

Table 85: Limited Exposure EO and ECH Residual Results for the 4076-110 model (Simulated Use) – DELP Tray

Residual Type	EO Residual Specification	Extraction Temperature	Components Extracted (pooled together)	Acceptance Criteria	*1X Results – 2 hrs. forced heat		**3X Results – 2,8,8 hrs. forced heat		***4X Results – 2,8,8,8 hrs. forced heat	
					Result (mg)	Pass /Fail	Result (mg)	Pass /Fail	Result (mg)	Pass /Fail
EO	Dose for first 24 hours not to exceed (average daily dose)	37°C	Stylet Assembly and Vein Lifter	4 mg	9.7×10^{-02}	Pass	3.43×10^{-02}	Pass	3.84×10^{-02}	Pass
	Blank Control – No EO exposure			N/A	1.0×10^{-02}	NA				
	Dose for first 24 hours not to exceed (average daily dose)	25°C	Stylet Guide and Pinch On Tool	4 mg	1.05×10^{-01}	Pass	2.47×10^{-02}	Pass	4.6×10^{-02}	Pass
	Blank Control – No EO exposure			N/A	1.5×10^{-02}	NA				
ECH	Dose for first 24 hours not to exceed (average daily dose)	37°C	Stylet Assembly and Vein Lifter	9 mg	1.06×10^{-02}	Pass	1.08×10^{-02}	Pass	1.08×10^{-02}	Pass
	Blank Control – No EO exposure			N/A	1.0×10^{-02}	NA				
	Dose for first 24 hours not to exceed (average daily dose)	25°C	Stylet Guide and Pinch On Tool	9 mg	1.06×10^{-02}	Pass	1.08×10^{-02}	Pass	1.08×10^{-02}	Pass
	Blank Control – No EO exposure			N/A	1.5×10^{-02}	NA				

*Reference Attachment 83. **Reference Attachment 85. ***Reference Attachment 87.

Table 86: 4076-110 Individual Component Surface Areas

Components	Surface Area (cm^2)	Quantity	Total Surface Area (cm^2)
Lead and Anchoring Sleeve - 599220016	68.92	1	68.92
Vein Lifter - 103548001	11.48	1	11.48
Stylet Assembly - 404028010	15.11	1	15.11
Stylet Assembly – 136529006	15.8	1	15.8
Stylet Guide - 105115001	2.58	1	2.58
Pinch On Tool - 800471001	28.37	2	56.74

Table 87: EO Tolerable Contact Limit for the 4076-110 Model – DELP Tray

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL ($\mu g/cm^2$)	$m_{dev,\ BSC}$ = *A* x TCL (µg)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,\ BSC}$ = *A* x TCL (mg)	Result $m_{dev,\ BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	68.92*	10	689.2	≤ 0.6892	0.67	Pass	84
	3x						0.28	Pass	86
	4x						0.16	Pass	88
Limited **	1x	37°C	42.39**		423.9	≤ 0.4239	0.097	Pass	83
	3x						0.03	Pass	85
	4x						0.04	Pass	87
Limited ***	1x	25°C	59.32***		593.2	≤ 0.5932	0.1	Pass	83
	3x						0.02	Pass	85
	4x						0.05	Pass	87

*The "Lead and anchoring sleeve"" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these componen portions together; see Table 86.
**The "Stylet Assemblies" and "Vein Lifter" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 86.
***The "Stylet Guide" and "Pinch-On Tools" were extracted using the simulated method at 25°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 86.

Table 88: ECH Tolerable Contact Limit for the 4076-110 Model – DELP Tray

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (mg/cm^2)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,\ BSC}$ = *A* x TCL (mg)	Result $m_{dev,\ BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	68.92*	5	≤ 344.6	0.01	Pass	84
	3x					0.01	Pass	86
	4x					0.01	Pass	88
Limited **	1x	37°C	42.39**		≤ 211.95	0.01	Pass	83
	3x					0.01	Pass	85
	4x					0.01	Pass	87
Limited ***	1x	25°C	59.32***		≤ 296.6	0.01	Pass	83
	3x					0.01	Pass	85
	4x					0.01	Pass	87

*****The "Lead and anchoring sleeve"" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these component portions together; see Table 86.
******The "Stylet Assemblies" and "Vein Lifter" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 86.
***The "Stylet Guide" and "Pinch-On Tools" were extracted using the simulated method at 25°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 86.

9.2.9 4296-88 Lead Model "Load Configuration I/I – DELP Trays"

Table 89: Sterilant Residual EO and ECH Analysis Results for the Permanent Contact Portions of the 4296-88 model (Exhaustive Extraction) – DELP Tray

Sterilant Residual Specification	Components Extracted (pooled together)	Residual Type	Acceptance Criteria	*1X Results – 8 hrs. forced heat		*4X Results – 8,8,8,8 hrs. forced heat	
				EO (mg)	Pass/Fail	EO (mg)	Pass/Fail
Dose for first 24 hours not to exceed	Lead and Anchor Sleeve	EO	4 mg	1.32	Pass	0.31	Pass
Dose for first 30 days not to exceed			60 mg	0.22	Pass	0.37	Pass
Lifetime dose not to exceed**			2500 mg	0.22	Pass	0.37	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.1 mg/day	8.6×10^{-06}	Pass	1.5×10^{-05}	Pass
				ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail
Dose for first 24 hours not to exceed		ECH	9 mg	0.009	Pass	0.006	Pass
Dose for first 30 days not to exceed			60 mg	0.029	Pass	0.006	Pass
Lifetime dose not to exceed**			10,000 mg	0.029	Pass	0.006	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.4 mg/day	1.2×10^{-06}	Pass	2.6×10^{-07}	Pass

* Reference Chemical Technologies REQ-090420-011 and 090421-010 (ref. section 4.0). Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The EO/ECH TCL results in the Table 89 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 4296 is compliant to ISO 10993-7:2008/AC:2009.

**Medtronic Chemical Technologies exhaustively extracts until the last residual extraction result is less than 10% of the first extraction result (taken at 24 hours), which represents the lifetime dose. Based on the results above, the reported 30 day dose is the same as the lifetime dose.

Table 90: Limited Exposure EO and ECH Residual Results for the 4296-88 model (Simulated Use) – DELP Tray

Residual Type	EO Residual Specification	Extraction Temperature	Components Extracted (pooled together)	Acceptance Acceptance Criteria	*1X Results – 8 hrs. forced heat		*4X Results – 8,8,8,8 hrs. forced heat	
					Result (mg)	Pass /Fail	Result (mg)	Pass /Fail
EO	Dose for first 24 hours not to exceed (average daily dose)	37°C	Subassembly Stylets, Steering Handle, Guidewire Clip and Guidewire Insertion Tool	4 mg	0.02	Pass	0.6	Pass
ECH	Dose for first 24 hours not to exceed (average daily dose)			9 mg	0.006	Pass	0.006	Pass

* Reference Chemical Technologies REQ-090420-011 and 090421-010 (ref. section 4.0). Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The EO/ECH results in the Table 90 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 4296 is compliant to ISO 10993-7:2008/AC:2009.

Table 91: 4296-88 Individual Component Surface Areas

Components	Surface Area (cm^2)	Quantity	Total Surface Area (cm^2)
Lead and Anchoring Sleeve – M940045A004	68.11	1	68.11
Subassembly Stylets – A16343002	13.47	1	13.47
Steering Handle – 177985001	35.04	1	35.04
Guidewire Clip – 177984001	24.36	1	24.36
Guidewire Insertion Tool – A13738001	18.64	1	18.64

Table 92: EO Tolerable Contact Limit for the 4296-88 Model – DELP Tray

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (µg/cm^2)	$m_{dev,\,BSC}$ = *A* x TCL (µg)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,\,BSC}$ = *A* x TCL (mg)	Result $m_{dev,\,BSC}$ (mg)	Pass/Fail	Reference
Permanent *	1x	37°C	68.11*	10	681.1	≤ 0.6811	0.22	Pass	***
	4x						0.37	Pass	***
Limited **	1x		91.51**		915.1	≤ 0.9151	0.02	Pass	***
	4x						0.60	Pass	***

*****The "Lead and anchoring sleeve"" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these componen portions together; see Table 91.

******The "Subassembly Stylets", "Steering Handle", "Guidewire Clip" and "Guidewire Insertion Tool" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 91.

***Reference Chemical Technologies REQ-090420-011 and 090421-010 (ref. section 4.0). Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The EO TCL results in the Table 92 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 4296 is compliant to ISO 10993-7:2008/AC:2009.

Table 93: ECH Tolerable Contact Limit for the 4296-88 Model – DELP Tray

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (mg/cm^2)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev, BSC} = A \times TCL$ (mg)	Result $m_{dev, BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	68.11*	5	≤ 340.5	0.029	Pass	***
	4x					0.006	Pass	***
Limited **	1x		91.51**		≤ 457.5	0.006	Pass	***
	4x					0.006	Pass	***

*****The "Lead and anchoring sleeve"" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these component portions together; see Table 91.

******The "Subassembly Stylets", "Steering Handle", "Guidewire Clip" and "Guidewire Insertion Tool" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 91.

***Reference Chemical Technologies REQ-090420-011 and 090421-010 (ref. section 4.0). Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The EO TCL results in the Table 93 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 4296 is compliant to ISO 10993-7:2008/AC:2009.

9.2.10 4195-103 Lead Model "Load Configuration I/I – DELP Trays"

Table 94: Sterilant Residual EO and ECH Analysis Results for the Permanent Contact Portions of the 4195-103 model (Exhaustive Extraction) – DELP Tray

Sterilant Residual Specification	Components Extracted (pooled together)	Residual Type	Acceptance Criteria	*1X Results – 8 hrs. forced heat		**3X Results – 8, 8, 8 hrs. forced heat		***4X Results – 8,8,8,8 hrs. forced heat	
				EO (mg)	Pass/Fail	EO (mg)	Pass/Fail	EO (mg)	Pass/Fail
Dose for first 24 hours not to exceed	Lead and Anchor Sleeve	EO	4 mg	1.78	Pass	2.06	Pass	2.27	Pass
Dose for first 30 days not to exceed			60 mg	2.18	Pass	2.38	Pass	2.60	Pass
Lifetime dose not to exceed****			2500 mg	2.18	Pass	2.38	Pass	2.60	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.1 mg/day	0.0	Pass	9.54×10^{-05}	Pass	1.04×10^{-04}	Pass
Blank Control – No EO exposure			N/A	0.01	N/A				
				ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail
Dose for first 24 hours not to exceed		ECH	9 mg	1.06×10^{-03}	Pass	1.08×10^{-03}	Pass	1.06×10^{-03}	Pass
Dose for first 30 days not to exceed			60 mg	1.06×10^{-03}	Pass	1.08×10^{-03}	Pass	1.06×10^{-03}	Pass
Lifetime dose not to exceed****			10,000 mg	1.06×10^{-03}	Pass	1.08×10^{-03}	Pass	1.06×10^{-03}	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.4 mg/day	4.24×10^{-08}	Pass	4.32×10^{-08}	Pass	4.24×10^{-08}	Pass
Blank Control – No EO exposure			N/A	1.0×10^{-03}	N/A				

*Reference Attachment 89. **Reference Attachment 91. ***Reference Attachment 93.
****Medtronic Chemical Technologies exhaustively extracts until the last residual extraction result is less than 10% of the first extraction result (taken at 24 hours), which represents the lifetime dose. Based on the results above, the reported 30 day dose is the same as the lifetime dose.

Table 95: Limited Exposure EO and ECH Residual Results for the 4195-103 model (Simulated Use) – DELP Tray

Residual Type	EO Residual Specification	Extraction Temperature	Components Extracted (pooled together)	Acceptance Acceptance Criteria	*1X Results – 8 hrs. forced heat		**3X Results – 8,8,8 hrs. forced heat		***4X Results – 8,8,8,8 hrs. forced heat	
					Result (mg)	Pass /Fail	Result (mg)	Pass /Fail	Result (mg)	Pass /Fail
EO	Dose for first 24 hours not to exceed (average daily dose)	37°C	Stylet Assembly and Vein Lifter	4 mg	2.09 x 10^{-02}	Pass	1.94 x 10^{-02}	Pass	2.37 x 10^{-02}	Pass
	Blank Control – No EO exposure			N/A	1.0 x 10^{-02}	NA				
	Dose for first 24 hours not to exceed (average daily dose)	25°C	Stylet Guide	4 mg	3.15 x 10^{-02}	Pass	1.02 x 10^{-01}	Pass	6.68 x 10^{-02}	Pass
	Blank Control – No EO exposure			N/A	1.5 x 10^{-02}	NA				
ECH	Dose for first 24 hours not to exceed (average daily dose)	37°C	Stylet Assembly and Vein Lifter	9 mg	1.06 x 10^{-02}	Pass	1.08 x 10^{-02}	Pass	1.06 x 10^{-02}	Pass
	Blank Control – No EO exposure			N/A	1.0 x 10^{-02}	NA				
	Dose for first 24 hours not to exceed (average daily dose)	25°C	Stylet Guide	9 mg	1.59 x 10^{-02}	Pass	1.62 x 10^{-02}	Pass	1.62 x 10^{-02}	Pass
	Blank Control – No EO exposure			N/A	1.5 x 10^{-02}	NA				

*Reference Attachment 89. **Reference Attachment 91. ***Reference Attachment 93.

Table 96: 4195-103 Individual Component Surface Areas

Components	Surface Area (cm^2)	Quantity	Total Surface Area (cm^2)
Lead and Anchoring Sleeve – M929699A006	65.77	1	65.77
Vein Lifter - 103548001	11.53	1	11.53
Stylet Assembly – M411059A007	10.45	1	10.45
Stylet Assembly – M411058A007	10.45	1	10.45
Stylet Assembly – M411057A008	9.65	2	19.3
Steering Handle - 177985001	35.05	1	35.05
Tool – Backloading/Frontloading – 184723001	13.15	2	26.3
Guidewire Clip – 177984001	24.32	1	48.64
Acute Retention Clip – A00980001	9.77	2	19.54

Table 97: EO Tolerable Contact Limit for the 4195-103 Model – DELP Tray

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL ($\mu g/cm^2$)	$m_{dev,BSC}$ = *A* x TCL (µg)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,BSC}$ = *A* x TCL (mg)	Result $m_{dev,BSC}$ (mg)	Pass/Fail	Reference
Permanent *	1x	37°C	65.77*	10	657.7	≤0.6577	1.51	****Fail	90
	3x						2.28	****Fail	92
	4x						1.82	****Fail	94
Limited **	1x	37°C	51.73**		517.3	≤0.5173	0.02	Pass	89
	3x						0.02	Pass	91
	4x						0.02	Pass	93
Limited ***	1x	25°C	129.53***		1295.3	≤1.2953	0.03	Pass	89
	3x						0.10	Pass	91
	4x						0.07	Pass	93

*The "Lead and anchoring sleeve"" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these componen portions together; see Table 96.
**The "Stylet Assemblies" and "Vein Lifter" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 96.
***The "Tool-Backloading/Frontloading", "Steering Handle", "Guidewire Clip" and Acute Retention Clip" were extracted using the simulated method at 25°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 96.

****All requirements must be met following single or multiple exposure(s) to an EO sterilization process. The 1X, 3X and 4X samples did not meet the tolerable contact limit requirements stated in ISO 10993-7:2008/AC:2009 (ref. section 4.0) for EO, however did meet the requirements for ECH. The requirements of ISO 10993-7:2008/AC:2009 clearly states that both sterilant residual levels and tolerable contact limits must be met. Should the tolerable contact limit not be achieved, irritation testing may be performed per ISO 10993-10 (ref. section 4.0). As the tolerable contact limit was not met, irritation testing was performed at the Medtronic Physiological Research Facility (PRL) and NAMSA. Biological evaluation report R000743 (ref. section 4.0) shows that the 4195-103 lead does not exhibit any evidence of significant irritation as processed for this application with a score of 0.0. Therefore, the 4195-103 does not exhibit irritation and is acceptable as per ISO 10993-10 (ref. section 4.0).

Table 98: ECH Tolerable Contact Limit for the 4195-103 Model – DELP Tray

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (mg/cm^2)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,BSC}$ = *A* x TCL (mg)	Result $m_{dev,BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	65.77*	5	≤328.85	0.005	Pass	90
	3x					0.01	Pass	92
	4x					0.005	Pass	94
Limited **	1x	37°C	51.73**		≤ 258.65	0.01	Pass	89
	3x					0.01	Pass	91
	4x					0.01	Pass	93
Limited ***	1x	25°C	129.53***		≤ 647.65	0.02	Pass	89
	3x					0.02	Pass	91
	4x					0.02	Pass	93

*The "Lead and anchoring sleeve"" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these component portions together; see Table 96.
**The "Stylet Assemblies" and "Vein Lifter" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 96.
***The "Tool-Backloading/Frontloading", "Steering Handle", "Guidewire Clip" and Acute Retention Clip" were extracted using the simulated method at 25°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 96.

9.3 Accessories and Adaptors EO/ECH and TCL Results

9.3.1 6717 Accessory Model "Load Configuration C/C – Pacing Accessory Trays"

Table 99: Sterilant Residual EO and ECH Analysis Results for the Permanent Contact Portions of the 6717 model (Exhaustive Extraction) – Accessory Tray

Sterilant Residual Specification	Components Extracted (pooled together)	Residual Type	Acceptance Criteria	*1X Results – 4 hrs. forced heat		**3X Results – 4, 8, 8 hrs. forced heat		***4X Results – 4,8,8,8 hrs. forced heat	
				EO (mg)	Pass/Fail	EO (mg)	Pass/Fail	EO (mg)	Pass/Fail
Dose for first 24 hours not to exceed	*Pin Plugs*	EO	4 mg	0.014	Pass	0.005	Pass	0.005	Pass
Dose for first 30 days not to exceed			60 mg	0.014	Pass	0.005	Pass	0.005	Pass
Lifetime dose not to exceed****			2500 mg	0.014	Pass	0.005	Pass	0.005	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.1 mg/day	5.7×10^{-07}	Pass	1.9×10^{-07}	Pass	1.9×10^{-07}	Pass
Blank Control – No EO exposure			N/A	0.005	N/A				
				ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail
Dose for first 24 hours not to exceed		ECH	9 mg	0.012	Pass	0.001	Pass	0.001	Pass
Dose for first 30 days not to exceed			60 mg	0.012	Pass	0.001	Pass	0.001	Pass
Lifetime dose not to exceed****			10,000 mg	0.012	Pass	0.001	Pass	0.001	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.4 mg/day	4.9×10^{-07}	Pass	4.3×10^{-08}	Pass	4.3×10^{-08}	Pass
Blank Control – No EO exposure			N/A	0.001	N/A				

*Reference Attachment 45. **Reference Attachment 47. ***Reference Attachment 49.
****Medtronic Chemical Technologies exhaustively extracts until the last residual extraction result is less than 10% of the first extraction result (taken at 24 hours), which represents the lifetime dose. Based on the results above, the reported 30 day dose is the same as the lifetime dose.

Table 100: 6717 Individual Component Surface Areas

Components	Surface Area (cm^2)	Quantity	Total Surface Area (cm^2)
Pin Plugs – 403582001	6.64	2	13.28

Table 101: EO Tolerable Contact Limit for the 6717 Model

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL ($\mu g/cm^2$)	$m_{dev,\ BSC}$ = *A* x TCL (µg)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,\ BSC}$ = *A* x TCL (mg)	Result $m_{dev,\ BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	13.28*	10	132.8	≤ 0.1328	0.005	Pass	46
	3x						0.005	Pass	48
	4x						0.005	Pass	50
*The "Pin Plugs"" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these component portions together see Table 100.									

Table 102: ECH Tolerable Contact Limit for the 6717 Model

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (mg/cm^2)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,\ BSC}$ = *A* x TCL (mg)	Result $m_{dev,\ BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	13.28*	5	≤ 66.4	0.01	Pass	46
	3x					0.005	Pass	48
	4x					0.005	Pass	50
*The "Pin Plugs"" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these component portions together; see Table 100.								

9.3.2 6295 Accessory Model "Load Configuration C/C – Pacing Accessory Trays"

Table 103: Limited Exposure EO and ECH Residual Results for the 6295 Lead (Simulated Use)

Residual Type	EO Residual Specification	Extraction Temperature	Components Extracted (pooled together)	Acceptance Criteria	*1X Results – 4 hrs. forced heat		**3X Results – 4,8,8 hrs. forced heat	
					Result (mg)	Pass /Fail	Result (mg)	Pass /Fail
EO	Dose for first 24 hours not to exceed (average daily dose)	25°C	Stylet guide, acute retention clip, backloading tool	4 mg	0.03	Pass	0.009	Pass
	Blank Control – No EO exposure			N/A	0.005	N/A		
ECH	Dose for first 24 hours not to exceed (average daily dose)	25°C	Stylet guide, acute retention clip, backloading tool	9 mg	0.005	Pass	0.005	Pass
	Blank Control – No EO exposure			N/A	0.005	N/A		

*Reference Attachment 51. **Reference Attachment 52.

Table 104: 6295 Individual Component Surface Areas

Lead Components	Surface Area (cm^2)	Quantity	Total Surface Area (cm^2)
Tool back-loading/front loading tool – 184723001	13.13	2	26.26
Acute retention clip – A00980001	9.77	2	19.54
Stylet guide - 170446001	7.60	2	15.2

Table 105: EO Tolerable Contact Limit for the 6295 Model

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (µg/cm^2)	$m_{dev,BSC}$ = *A* x TCL (µg)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,BSC}$ = *A* x TCL (mg)	Result $m_{dev,BSC}$ (mg)	Pass/Fail	Attachment
Limited *	1x	25°C	*61	10	610	≤ 0.610	0.03	Pass	51
	3x						0.009	Pass	52

*The "tool back-loading/front loading tool", "acute retention clip" and "stylet guide" were extracted using the simulated method at 25°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 104.

Table 106: ECH Tolerable Contact Limit for the 6295 Model

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (mg/cm^2)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev, BSC}$ = *A* x TCL (mg)	Result $m_{dev, BSC}$ (mg)	Pass/Fail	Attachment
Limited *	1x	25°C	*61	5	≤ 305	0.005	Pass	51
	3x					0.005	Pass	52

***The "tool back-loading/front loading tool", "acute retention clip" and "stylet guide" were extracted using the simulated method at 25°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 104.

9.3.3 6986M-39 Accessory Model "Load Configuration A/A – Standard Lead Trays"

Table 107: Sterilant Residual EO and ECH Analysis Results for the Permanent Contact Portions of the 6986M-39 Extender (Exhaustive Extraction)

Sterilant Residual Specification	Components Extracted (pooled together)	Residual Type	Acceptance Criteria	*1X Results – 4 hrs. forced heat		**3X Results – 4,8,8 hrs. forced heat	
				EO (mg)	Pass/fail	EO (mg)	Pass/fail
Dose for first 24 hours not to exceed	*Extender and Adhesive*	EO	4 mg	0.05	Pass	0.05	Pass
Dose for first 30 days not to exceed			60 mg	0.05	Pass	0.06	Pass
Lifetime dose not to exceed***			2500 mg	0.05	Pass	0.06	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/ AC:2009 (ref. section 4.0)]}			0.1 mg/day	1.9×10^{-06}	Pass	2.4×10^{-06}	Pass
Blank Control – No EO exposure			N/A	0.02	N/A		
				ECH (mg)	Pass/fail	ECH (mg)	Pass/fail
Dose for first 24 hours not to exceed		ECH	9 mg	0.05	Pass	0.02	Pass
Dose for first 30 days not to exceed			60 mg	0.06	Pass	0.02	Pass
Lifetime dose not to exceed***			10,000 mg	0.06	Pass	0.02	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/ AC:2009 (ref. section 4.0)]}			0.4 mg/day	2.3×10^{-06}	Pass	9.4×10^{-07}	Pass
Blank Control – No EO exposure			N/A	0.02	N/A		

*Reference Attachment 53. **Reference Attachment 55.
Chemical Technologies had to extract the adhesive and extender separately from one another in order to prevent adhesive build up within the gas chromatograph. Therefore, the EO and ECH results for the extender and adhesive were combined in order to provide a total EO and ECH for the permanent contact components.

***Medtronic Chemical Technologies exhaustively extracts until the last residual extraction result is less than 10% of the first extraction result (taken at 24 hours), which represents the lifetime dose. Based on the results above, the reported 30 day dose is the same as the lifetime dose.

Table 108: Limited Exposure EO and ECH Residual Results for the 6986M-39 Lead (Simulated Use)

Residual Type	EO Residual Specification	Extraction Temperature	Components Extracted (pooled together)	Acceptance Criteria	*1X Results – 4 hrs. forced heat		**3X Results – 4,8,8 hrs. forced heat	
					Result (mg)	Pass /Fail	Result (mg)	Pass /Fail
EO	Dose for first 24 hours not to exceed (average daily dose)	25°C	Hex wrench, Screw Mach Set, Cap Tube	4 mg	0.005	Pass	0.009	Pass
	Blank Control – No EO exposure			N/A	0.005	NA		
ECH	Dose for first 24 hours not to exceed (average daily dose)			9 mg	0.005	Pass	0.01	Pass
	Blank Control – No EO exposure			N/A	0.005	NA		

*Reference Attachment 53. **Reference Attachment 55.

Table 109: 6986M-39 Individual Component Surface Areas

Lead Components	Surface Area (cm^2)	Quantity	Total Surface Area (cm^2)
Extender - 501770002	37.90	1	37.90
Adhesive - 168014002	42.45	1	42.45
Hex Wrench – 800523001	3.27	4	13.08
Screw Mach Set – 110918107	0.23	4	0.92
Cap Tube – 102025002	12.28	1	12.28

Table 110: EO Tolerable Contact Limit for the 6986M-39 Leads

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (µg/cm^2)	$m_{dev,BSC}$ = *A* x TCL (µg)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,BSC}$ = *A* x TCL (mg)	Result $m_{dev,BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	80.35*	10	803.5	≤ 0.8035	***0.04	Pass	54
	3x						***0.06	Pass	56
Limited**	1x	25°C	26.28**		262.8	≤ 0.2628	0.005	Pass	53
	3x						0.009	Pass	55

*The "Extender" and "Adhesive" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these component portions together; see Table 109.

**The "Hex wrench", "Cap tube" and "Screw mach set" component portions were pooled together and extracted using the "simulated use" method at 25°C for 1 hour. Therefore, the surface calculation shown is derived by combining these component portions together; see Table 109.

***Chemical Technologies had to extract the adhesive and extender separately from one another in order to prevent adhesive build up within the gas chromatograph. Therefore, the TCL results for the extender and adhesive were combined in order to provide a total TCL for the permanent contact components.

Table 111: ECH Tolerable Contact Limit for the 6986M-39 Leads

Device	# Times	Extraction	*A* (cm^2)	TCL	Adjusted TCL	Result	Pass/Fail	Attachment

Exposure Category	Sterilized	Temperature		(mg/cm²)	Acceptance Criteria Based on TCL Value - $m_{dev, BSC}$ = A x TCL (mg)	$m_{dev, BSC}$ (mg)		
Permanent *	1x	37°C	80.35*	5	≤ 401.75	***0.04	Pass	54
	3x					***0.02	Pass	56
Limited**	1x	25°C	26.28**		≤ 131.4	0.005	Pass	53
	3x					0.01	Pass	55

*The "Extender" and "Adhesive" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these component portions together; see Table 109.
** The "Hex wrench", "Cap tube" and "Screw mach set" component portions were pooled together and extracted using the "simulated use" method at 25°C for 1 hour. Therefore, the surface calculation shown is derived by combining these component portions together; see Table 109.
***Chemical Technologies had to extract the adhesive and extender separately from one another in order to prevent adhesive build up within the gas chromatograph. Therefore, the TCL results for the extender and adhesive were combined in order to provide a total TCL for the permanent contact components.

9.3.4 6093 Stylet Model "Load Configuration P – Stylet Pouches"

Table 112: Limited Exposure EO and ECH Residual Results for the 6093 Lead (Simulated Use)

Residual Type	EO Residual Specification	Extraction Temperature	Components Extracted (pooled together)	Acceptance Criteria	*1X Results – 4 hrs. forced heat		**3X Results – 4,8,8 hrs. forced heat	
					Result (mg)	Pass /Fail	Result (mg)	Pass /Fail
EO	Dose for first 24 hours not to exceed (average daily dose)	25°C	Stylet guide	4 mg	0.005	Pass	0.005	Pass
	Blank Control – No EO exposure			N/A	0.005	NA		
	Dose for first 24 hours not to exceed (average daily dose)	37°C	Stylet	4 mg	0.01	Pass	0.006	Pass
	Blank Control – No EO exposure			N/A	0.01	NA		
ECH	Dose for first 24 hours not to exceed (average daily dose)	25°C	Stylet guide	9 mg	0.005	Pass	0.005	Pass
	Blank Control – No EO exposure			N/A	0.005	NA		
	Dose for first 24 hours not to exceed (average daily dose)	37°C	Stylet	9 mg	0.005	Pass	0.005	Pass
	Blank Control – No EO exposure			N/A	0.01	NA		

*Reference Attachment 57. **Reference Attachment 58.

Table 113: 6093 Individual Component Surface Areas

Lead Components	Surface Area (cm^2)	Quantity	Total Surface Area (cm^2)
Stylet – 404247004	9.84	2	19.68
Stylet Guide - 105115001	2.58	2	5.16

Table 114: EO Tolerable Contact Limit for the 6093 Leads

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (µg/cm^2)	$m_{dev, BSC}$ = *A* x TCL (µg)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev, BSC}$ = *A* x TCL (mg)	Result $m_{dev, BSC}$ (mg)	Pass/Fail	Attachment
Limited *	1x	37°C	19.68*	10	196.8	≤ 0.1968	0.01	Pass	57
	3x						0.006	Pass	58
Limited**	1x	25°C	5.16**		51.6	≤ 0.0516	0.005	Pass	57
	3x						0.005	Pass	58

*****The "Stylets" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 113.
** The "Stylet guide" component was extracted using the "simulated use" method at 25°C for 1 hour. See Table 113 for surface area.

Table 115: ECH Tolerable Contact Limit for the 6093 Leads

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (mg/cm^2)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev, BSC}$ = *A* x TCL (mg)	Result $m_{dev, BSC}$ (mg)	Pass/Fail	Attachment
Limited *	1x	37°C	19.68*	5	≤ 98.4	0.005	Pass	57
	3x					0.005	Pass	58
Limited**	1x	25°C	5.16**		≤ 25.8	0.005	Pass	57
	3x					0.005	Pass	58

*****The "Stylets" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 113.
** The "Stylet guide" component was extracted using the "simulated use" method at 25°C for 1 hour. See Table 113 for surface area.

9.3.5 6056 Accessory Model "Load Configuration C/C – Pacing Accessory Trays"

Table 116: Limited Exposure EO and ECH Residual Results for the 6056 Lead (Simulated Use)

Residual Type	EO Residual Specification	Extraction Temperature	Components Extracted (pooled together)	Acceptance Criteria	*1X Results – 4 hrs. forced heat		**3X Results – 4,8,8 hrs. forced heat	
					Result (mg)	Pass /Fail	Result (mg)	Pass /Fail
EO	Dose for first 24 hours not to exceed (average daily dose)	25°C	Pinch on Tool/Stylet Guide and Rotation Tool/Stylet Guide	4 mg	0.02	Pass	0.01	Pass
	Blank Control – No EO exposure			N/A	0.005	N/A		
ECH	Dose for first 24 hours not to exceed (average daily dose)			9 mg	0.005	Pass	0.005	Pass
	Blank Control – No EO exposure			N/A	0.005	N/A		

*Reference Attachment 59. **Reference Attachment 60.

Table 117: 6056 Individual Component Surface Areas

Lead Components	Surface Area (cm^2)	Quantity	Total Surface Area (cm^2)
Pinch on Tool/Stylet Guide – 800471001	28.37	1	28.37
Rotation Tool/Stylet Guide - 184292001	9.66	1	9.66

Table 118: EO Tolerable Contact Limit for the 6056 Leads

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL ($\mu g/cm^2$)	$m_{dev, BSC}$ = *A* x TCL (µg)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev, BSC}$ = *A* x TCL (mg)	Result $m_{dev, BSC}$ (mg)	Pass/Fail	Attachment
Limited *	1x	25°C	38.03*	10	380.3	≤ 0.3803	0.02	Pass	59
	3x						0.01	Pass	60

*The "Pinch on Tool/Stylet Guide" and "Rotation Tool/Stylet Guide" were extracted using the simulated method at 25°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 117.

Table 119: ECH Tolerable Contact Limit for the 6056 Leads

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (mg/cm^2)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev, BSC}$ = *A* x TCL (mg)	Result $m_{dev, BSC}$ (mg)	Pass/Fail	Attachment
Limited *	1x	25°C	38.03*	5	≤ 190.15	0.005	Pass	59
	3x					0.005	Pass	60

***The "Pinch on Tool/Stylet Guide" and "Rotation Tool/Stylet Guide" were extracted using the simulated method at 25°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 117.

9.3.6 6052 Stylet Model – "Load Configuration P – Stylet Pouches"

Table 120: Limited Exposure EO and ECH Residual Results for the 6052 Stylet Model (Simulated Use) – Stylet pouch

Residual Type	EO Residual Specification	Extraction Temperature	Components Extracted (pooled together)	Acceptance Criteria	*1X Results – 4 hrs. forced heat		**3X Results – 4,8,8 hrs. forced heat	
					Result (mg)	Pass /Fail	Result (mg)	Pass /Fail
EO	Dose for first 24 hours not to exceed (average daily dose)	25°C	Stylet guide	4 mg	0.005	Pass	0.005	Pass
		37°C	Stylet		0.01	Pass	0.009	Pass
	Blank Control – No EO exposure		Stylet, and Stylet guide	N/A	0.005	N/A		
ECH	Dose for first 24 hours not to exceed (average daily dose)	25°C	Stylet guide	9 mg	0.005	Pass	0.005	Pass
		37°C	Stylet		0.005	Pass	0.005	Pass
	Blank Control – No EO exposure		Stylet and Stylet guide	N/A	0.005	N/A		

*Reference Attachment 61. **Reference Attachment 62.

Table 121: 6052 Individual Component Surface Areas

Lead Components	Surface Area (cm^2)	Quantity	Total Surface Area (cm^2)
Stylet - 599634003	9.03	2	18.06
Stylet Guide - 105115001	2.58	2	5.16

Table 122: EO Tolerable Contact Limit for the 6052 Stylet Model – Stylet pouch

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL ($\mu g/cm^2$)	$m_{dev, BSC}$ = *A* x TCL (µg)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev, BSC}$ = *A* x TCL (mg)	Result $m_{dev, BSC}$ (mg)	Pass/Fail	Attachment
Limited *	1x	37°C	18.06*	10	180.6	≤ 0.1806	0.01	Pass	61
	3x						0.009	Pass	62
Limited**	1x	25°C	5.16**		51.6	≤ 0.0516	0.005	Pass	61
	3x						0.005	Pass	62

*The "Stylets" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 121.
**The "Stylet guide" component was extracted using the "simulated use" method at 25°C for 1 hour. See Table 121 for surface area.

Table 123: ECH Tolerable Contact Limit for the 6052 Stylet Model – Stylet pouch

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (mg/cm^2)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev, BSC}$ = *A* x TCL (mg)	Result $m_{dev, BSC}$ (mg)	Pass/Fail	Attachment
Limited *	1x	37°C	19.68*	5	≤ 98.4	0.005	Pass	61
	3x					0.005	Pass	62
Limited**	1x	25°C	5.16**		≤ 25.8	0.005	Pass	61
	3x					0.005	Pass	62

*The "Stylets" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 121.
**The "Stylet guide" component was extracted using the "simulated use" method at 25°C for 1 hour. See Table 121 for surface area.

9.3.7 6052 Stylet Model – "Load Configuration A/A – Standard Lead Trays"

Table 124: Limited Exposure EO and ECH Residual Results for the 6052 Stylet Model (Simulated Use) - Standard lead tray

Residual Type	EO Residual Specification	Extraction Temperature	Components Extracted (pooled together)	Acceptance Criteria	*1X Results – 4 hrs. forced heat		**3X Results – 4,8,8 hrs. forced heat	
					Result (mg)	Pass /Fail	Result (mg)	Pass /Fail
EO	Dose for first 24 hours not to exceed (average daily dose)	25°C	Stylet guide	4 mg	0.005	Pass	0.005	Pass
		37°C	Stylets		0.009	Pass	0.009	Pass
	Blank Control – No EO exposure		Stylet guide and Stylets	N/A	0.005	N/A		
ECH	Dose for first 24 hours not to exceed (average daily dose)	25°C	Stylet guide	9 mg	0.005	Pass	0.005	Pass
		37°C	Stylets		0.005	Pass	0.005	Pass
	Blank Control – No EO exposure		Stylet guide and Stylets	N/A	0.005	N/A		

*Reference Attachment 63. **Reference Attachment 64.

Table 125: 6052 Individual Component Surface Areas

Lead Components	Surface Area (cm^2)	Quantity	Total Surface Area (cm^2)
Stylet - 599634003	9.03	2	18.06
Stylet Guide - 105115001	2.58	2	5.16

Table 126: EO Tolerable Contact Limit for the 6052 Stylet Model - Standard lead tray

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (µg/cm^2)	$m_{dev,BSC}$ = *A* x TCL (µg)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,BSC}$ = *A* x TCL (mg)	Result $m_{dev,BSC}$ (mg)	Pass/Fail	Attachment
Limited *	1x	37°C	18.06*	10	180.6	≤ 0.1806	0.009	Pass	63
	3x						0.009	Pass	64
Limited**	1x	25°C	5.16**		51.6	≤ 0.0516	0.005	Pass	63
	3x						0.005	Pass	64

*****The "Stylets" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 125.
** The "Stylet guide" component was extracted using the "simulated use" method at 25°C for 1 hour. See Table 125 for surface area.

Table 127: ECH Tolerable Contact Limit for the 6052 Stylet Model - Standard lead tray

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (mg/cm^2)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,BSC}$ = *A* x TCL (mg)	Result $m_{dev,BSC}$ (mg)	Pass/Fail	Attachment
Limited *	1x	37°C	19.68*	5	≤ 98.4	0.005	Pass	63
	3x					0.005	Pass	64
Limited**	1x	25°C	5.16**		≤ 25.8	0.005	Pass	63
	3x					0.005	Pass	64

*****The "Stylets" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 125.
** The "Stylet guide" component was extracted using the "simulated use" method at 25°C for 1 hour. See Table 125 for surface area.

9.3.8 5866-24M Accessory Model "Load Configuration C/C – Pacing Accessory Tray"

Table 128: Sterilant Residual EO and ECH Analysis Results for the Permanent Contact Portions of the 5866-24M Accessory Model (Exhaustive Extraction)

Sterilant Residual Specification	Component Extracted	Residual Type	Acceptance Criteria	*1X Results – 4 hrs. forced heat		*3X Results – 4,8,8 hrs. forced heat	
				EO (mg)	Pass/Fail	EO (mg)	Pass/Fail
Dose for first 24 hours not to exceed	Adaptor and Medical Adhesive	EO	4 mg	0.01	Pass	0.01	Pass
Dose for first 30 days not to exceed			60 mg	0.02	Pass	0.01	Pass
Lifetime dose not to exceed**			2500 mg	0.02	Pass	0.01	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008 (ref. section 4.0)]}			0.1 mg/day	8.0×10^{-07}	Pass	4.0×10^{-07}	Pass
				ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail
Dose for first 24 hours not to exceed		ECH	9 mg	0.003	Pass	0.001	Pass
Dose for first 30 days not to exceed			60 mg	0.003	Pass	0.001	Pass
Lifetime dose not to exceed**			10,000 mg	0.003	Pass	0.001	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008 (ref. section 4.0)]}			0.4 mg/day	1.1×10^{-07}	Pass	5.0×10^{-08}	Pass

* Reference Certification 1119 issue 3L (ref. section 4.0). Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The EO/ECH results in the Table 128 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 5866-24M is compliant to ISO 10993-7:2008/AC:2009.

**Reference Attachment 37.

**Medtronic Chemical Technologies exhaustively extracts until the last residual extraction result is less than 10% of the first extraction result (taken at 24 hours), which represents the lifetime dose. Based on the results above, the reported 30 day dose is the same as the lifetime dose.

Table 129: Limited Exposure EO and ECH Residual Results for the 5866-24M Accessory Model (Simulated Use)

Residual Type	EO Residual Specification	Extraction Temperature	Components Extracted (pooled together)	Acceptance Acceptance Criteria	*1X Results – 4 hrs. forced heat		*3X Results – 4,8,8 hrs. forced heat	
					Result (mg)	Pass /Fail	Result (mg)	Pass /Fail
EO	Dose for first 24 hours not to exceed (average daily dose)	37°C	Hex Wrenches, Screw Mach Set and Cap Tube	4 mg	0.002	Pass	0.001	Pass
ECH	Dose for first 24 hours not to exceed (average daily dose)			9 mg	0.002	Pass	0.001	Pass

* Reference Certification 1119 issue 3L (ref. section 4.0). Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The EO/ECH results in the Table 129 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 5866-24M is compliant to ISO 10993-7:2008/AC:2009.

Table 130: 5866-24M Individual Component Surface Areas

Components	Surface Area (cm^2)	Quantity	Total Surface Area (cm^2)
Adaptor – 501695002	32.15	1	32.15
Hex Wrenches – 800523001	3.27	4	13.08
Screw Mach Set - 110918107	0.23	4	0.92
Cap Tube – 102025002	12.28	1	12.28
Medical Adhesive – 168014002	42.45	1	42.45

Table 131: EO Tolerable Contact Limit for the 5866-24M Accessory Model

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (µg/cm^2)	$m_{dev, BSC}$ = *A* x TCL (µg)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev, BSC}$ = *A* x TCL (mg)	Result $m_{dev, BSC}$ (mg)	Pass/Fail	Reference
Permanent *	1x	37°C	74.6*	10	746	≤ 0.746	0.02	Pass	***
	3x						0.01	Pass	***
Limited **	1x		68.73**		687.3	≤ 0.6873	0.002	Pass	***
	3x						0.001	Pass	***

***** The "Adaptor" and "Medical Adhesive" were extracted using the exhaustive method at 37°C.

****** The "Hex Wrenches", "Screw Mach Set" and "Cap Tube" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 130.

*** Reference Certification 1119 issue 3L (ref. section 4.0). Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The EO TCL results in the Table 130 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 5866-24M is compliant to ISO 10993-7:2008/AC:2009.

Table 132: ECH Tolerable Contact Limit for the 5866-24M Accessory Model

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (mg/cm^2)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev, BSC}$ = *A* x TCL (mg)	Result $m_{dev, BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	74.6*	5	≤ 373	0.003	Pass	***
	3x					0.001	Pass	***
Limited **	1x		68.73**		≤ 343.65	0.002	Pass	***
	3x					0.001	Pass	***

*****The "Adaptor" and "Medical Adhesive" were extracted using the exhaustive method at 37°C.
******The "Hex Wrenches", "Screw Mach Set" and "Cap Tube" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 130.
*** Reference Certification 1119 issue 3L (ref. section 4.0). Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The ECH TCL results in the Table 130 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 5866-24M is compliant to ISO 10993-7:2008/AC:2009.

9.3.9 5866-22 Accessory Model "Load Configuration C/C – Pacing Accessory Tray"

Table 133: Sterilant Residual EO and ECH Analysis Results for the Permanent Contact Portions of the 5866-22 Accessory Model (Exhaustive Extraction)

Sterilant Residual Specification	Component Extracted	Residual Type	Acceptance Criteria	*1X Results – 4 hrs. forced heat		*3X Results – 4,8,8 hrs. forced heat	
				EO (mg)	Pass/Fail	EO (mg)	Pass/Fail
Dose for first 24 hours not to exceed	Adaptor and Medical Adhesive	EO	4 mg	0.51	Pass	0.41	Pass
Dose for first 30 days not to exceed			60 mg	0.51	Pass	0.41	Pass
Lifetime dose not to exceed**			2500 mg	0.51	Pass	0.41	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.1 mg/day	2.0×10^{-05}	Pass	1.6×10^{-05}	Pass
				ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail
Dose for first 24 hours not to exceed		ECH	9 mg	0.1	Pass	***<MDLD	Pass
Dose for first 30 days not to exceed			60 mg	0.1	Pass	***<MDLD	Pass
Lifetime dose not to exceed**			10,000 mg	0.1	Pass	***<MDLD	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.4 mg/day	4.0×10^{-06}	Pass	***<MDLD	Pass

* Reference DL952821.A (ref. section 4.0). Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The EO/ECH results in the Table 133 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 5866-22 is compliant to ISO 10993-7:2008/AC:2009.
**Medtronic Chemical Technologies exhaustively extracts until the last residual extraction result is less than 10% of the first extraction result (taken at 24 hours), which represents the lifetime dose. Based on the results above, the reported 30 day dose is the same as the lifetime dose.

***MDLD= Method Detection Limit for device. ECH dose was too low to detect for measurement.

Table 134: Limited Exposure EO and ECH Residual Results for the 5866-22 Accessory Model (Simulated Use)

Residual Type	EO Residual Specification	Extraction Temperature	Components Extracted (pooled together)	Acceptance Acceptance Criteria	*1X Results – 4 hrs. forced heat		*3X Results – 4,8,8 hrs. forced heat	
					Result (mg)	Pass /Fail	Result (mg)	Pass /Fail
EO	Dose for first 24 hours not to exceed (average daily dose)	37°C	Hex Wrenches, Screw Mach Set and Cap Tube	4 mg	0.06	Pass	0.06	Pass
ECH	Dose for first 24 hours not to exceed (average daily dose)			9 mg	**<MDLD	Pass	**<MDLD	Pass

* Reference DL952821.A (ref. section 4.0). Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The EO/ECH results in the Table 134 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 5866-22 is compliant to ISO 10993-7:2008/AC:2009.

**MDLD= Method Detection Limit for device. ECH dose was too low to detect for measurement.

Table 135: 5866-22 Individual Component Surface Areas

Components	Surface Area (cm^2)	Quantity	Total Surface Area (cm^2)
Adaptor – 501009003	21.69	1	21.69
Hex Wrenches – 800523001	3.27	4	13.08
Screw Mach Set - 110925003	0.17	4	0.68
Cap Tube – 102025002	12.28	1	12.28
Medical Adhesive – 168014002	42.45	1	42.45

Table 136: EO Tolerable Contact Limit for the 5866-22 Accessory Model

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (µg/cm^2)	$m_{dev,BSC}$ = *A* x TCL (µg)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,BSC}$ = *A* x TCL (mg)	Result $m_{dev,BSC}$ (mg)	Pass/Fail	Reference
Permanent *	1x	37°C	64.14*	10	641.4	≤ 0.6414	0.51	Pass	***
	3x						0.41	Pass	***
Limited **	1x		90.18**		901.8	≤0.9018	0.06	Pass	***
	3x						0.06	Pass	***

*****The "Adaptor" and "Medical Adhesive" were extracted using the exhaustive method at 37°C.

******The "Hex Wrenches", "Screw Mach Set" and "Cap Tube" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 135.

*** Reference DL952821.A (ref. section 4.0). Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The EO results in the Table 136 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 5866-22 is compliant to ISO 10993-7:2008/AC:2009.

Table 137: ECH Tolerable Contact Limit for the 5866-22 Accessory Model

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (mg/cm^2)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev, BSC}$ = *A* x TCL (mg)	Result $m_{dev, BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	64.14*	5	≤ 320.7	0.1	Pass	****
	3x					***<MDLD	Pass	****
Limited **	1x		90.18**		≤ 450.9	***<MDLD	Pass	****
	3x					***<MDLD	Pass	****

The "Adaptor" and "Medical Adhesive" were extracted using the exhaustive method at 37°C.
**The "Hex Wrenches", "Screw Mach Set" and "Cap Tube" were extracted using the simulated method at 37°C for 1 hour. The surface calculation shown is derived by combining these component portions together; see Table 135.
*** Reference DL952821.A (ref. section 4.0). Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The EO results in the Table 137 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 5866-22 is compliant to ISO 10993-7:2008/AC:2009.

9.3.10 5866-46 Accessory Model "Load Configuration C/C – Pacing Accessory Tray"

Table 138: Sterilant Residual EO and ECH Analysis Results for the Permanent Contact Portions of the 5866-46 Accessory Model (Exhaustive Extraction)

Sterilant Residual Specification	Component Extracted	Residual Type	Acceptance Criteria	*1X Results – 48 hrs. forced heat		*3X Results – 48,48,48 hrs. forced heat	
				EO (mg)	Pass/Fail	EO (mg)	Pass/Fail
Dose for first 24 hours not to exceed	Adaptor	EO	4 mg	0.02	Pass	0.02	Pass
Dose for first 30 days not to exceed			60 mg	0.04	Pass	0.06	Pass
Lifetime dose not to exceed**			2500 mg	0.04	Pass	0.06	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.1 mg/day	1.6×10^{-06}	Pass	2.4×10^{-06}	Pass
				ECH (mg)	**Pass/Fail**	**ECH (mg)**	**Pass/Fail**
Dose for first 24 hours not to exceed		ECH	9 mg	0.0013	Pass	0.003	Pass
Dose for first 30 days not to exceed			60 mg	0.0013	Pass	0.003	Pass
Lifetime dose not to exceed**			10,000 mg	0.0013	Pass	0.003	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.4 mg/day	5.2×10^{-08}	Pass	1.2×10^{-07}	Pass

* Reference Certification 1119 issue 3K and Minneapolis Chemical Technologies MAQS # 080313006 (ref. section 4.0). Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The EO results in the Table 138 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 5866-46 is compliant to ISO 10993-7:2008/AC:2009.

**Medtronic Chemical Technologies exhaustively extracts until the last residual extraction result is less than 10% of the first extraction result (taken at 24 hours), which represents the lifetime dose. Based on the results above, the reported 30 day dose is the same as the lifetime dose.

Table 139: 5866-46 Individual Component Surface Areas

Components	Surface Area (cm^2)	Quantity	Total Surface Area (cm^2)
Connector Sleeve – 403669001	5.11	2	10.22
Connector Sleeve – 403697001	5.94	2	11.88

Table 140: EO Tolerable Contact Limit for the 5866-46 Accessory Model

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (µg/cm^2)	$m_{dev,BSC}$ = *A* x TCL (µg)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,BSC}$ = *A* x TCL (mg)	Result $m_{dev,BSC}$ (mg)	Pass/Fail	Reference
Permanent *	1x	37°C	22.1*	10	221	≤ 0.221	0.04	Pass	**
	3x						0.06	Pass	**

*****The "connector sleeves" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these component portions together; see Table 139.

**Reference Certification 1119 issue 3K and Minneapolis Chemical Technologies MAQS # 080313006 (ref. section 4.0). Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The EO results in the Table 140 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 5866-46 is compliant to ISO 10993-7:2008/AC:2009.

Table 141: ECH Tolerable Contact Limit for the 5866-46 Accessory Model

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (mg/cm^2)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,BSC}$ = *A* x TCL (mg)	Result $m_{dev,BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	22.1*	5	≤ 110.5	0.001	Pass	**
	3x					0.003	Pass	**

*****The "connector sleeves" were extracted using the exhaustive method at 37°C. The surface calculation shown is derived by combining these component portions together; see Table 139.

**Reference Certification 1119 issue 3K and Minneapolis Chemical Technologies MAQS # 080313006 (ref. section 4.0). Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The EO results in the Table 141 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 5866-46 is compliant to ISO 10993-7:2008/AC:2009.

9.4 TDS Drug Delivery Catheter EO/ECH and TCL Results

9.4.1 10642/8201-80 Catheter "Load Configuration I/I – DELP Tray"

NOTE: Qualification of the 120cm length 8201 has been performed since the last revision (issue c) of this report (See report BL0021882). Model # 10642 was only used for Clinical use and model # 8201 is the Market release #.

Table 142: Sterilant Residual EO and ECH Analysis Results for the Permanent Contact Portions of the 10642/8201-80 Catheter (Exhaustive Extraction)

Sterilant Residual Specification	Component Extracted	Residual Type	Acceptance Criteria	*1X Results – 4 hrs. forced heat		*3X Results – 4,8,8 hrs. forced heat	
				EO (mg)	Pass/Fail	EO (mg)	Pass/Fail
Dose for first 24 hours not to exceed	Catheter	EO	4 mg	0.04	Pass	0.21	Pass
Dose for first 30 days not to exceed			60 mg	0.06	Pass	0.26	Pass
Lifetime dose not to exceed**			2500 mg	0.06	Pass	0.26	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.1 mg/day	2.3×10^{-06}	Pass	1.0×10^{-05}	Pass
				ECH (mg)	Pass/Fail	ECH (mg)	Pass/Fail
Dose for first 24 hours not to exceed		ECH	9 mg	0.01	Pass	0.004	Pass
Dose for first 30 days not to exceed			60 mg	0.005	Pass	0.004	Pass
Lifetime dose not to exceed**			10,000 mg	0.005	Pass	0.004	Pass
Average daily dose not to exceed {M_d/25,000 where M_d is extract residue [ref. ISO 10993-7:2008/AC:2009 (ref. section 4.0)]}			0.4 mg/day	1.9×10^{-07}	Pass	1.6×10^{-07}	Pass

*Reference BL0020404 and Minneapolis Chemical Technologies REQ-090826-007 (ref. section 4.0). Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The EO results in the Table 142 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 10642/8201 is compliant to ISO 10993-7:2008/AC:2009.

**Medtronic Chemical Technologies exhaustively extracts until the last residual extraction result is less than 10% of the first extraction result (taken at 24 hours), which represents the lifetime dose. Based on the results above, the reported 30 day dose is the same as the lifetime dose.

Table 143: 10642/8201-80 Individual Component Surface Areas

Components	Surface Area (cm^2)	Quantity	Total Surface Area (cm^2)
Catheter	54.84	1	54.84

Table 144: EO Tolerable Contact Limit for the 10642/8201-80 Catheter

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL ($\mu g/cm^2$)	$m_{dev,BSC}$ = *A* x TCL (µg)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,BSC}$ = *A* x TCL (mg)	Result $m_{dev,BSC}$ (mg)	Pass/Fail	Reference
Permanent *	1x	37°C	54.84*	10	548.4	≤ 0.5484	0.06	Pass	**
	3x						0.26	Pass	**

*****The "catheter" was extracted using the exhaustive method at 37°C.
**Reference BL0020404 and Minneapolis Chemical Technologies REQ-090826-007 (ref. section 4.0). Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The EO results in the Table 144 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 10642/8201 is compliant to ISO 10993-7:2008/AC:2009.

Table 145: ECH Tolerable Contact Limit for the 10642/8201-80 Catheter

Device Exposure Category	# Times Sterilized	Extraction Temperature	*A* (cm^2)	TCL (mg/cm^2)	Adjusted TCL Acceptance Criteria Based on TCL Value - $m_{dev,BSC}$ = *A* x TCL (mg)	Result $m_{dev,BSC}$ (mg)	Pass/Fail	Attachment
Permanent *	1x	37°C	54.84*	5	≤ 274.2	0.005	Pass	**
	3x					0.004	Pass	**

*****The "catheter" was extracted using the exhaustive method at 37°C.
**Reference BL0020404 and Minneapolis Chemical Technologies REQ-090826-007 (ref. section 4.0). Residual analysis testing was performed per CSS-1001-XXXX-0036 per ISO 10993:1995. Comparison of this test method (CSS-1001-XXXX-0036) to the new compliant test method CHEMWI0219 per ISO 10993-7:2008/AC:2009 shows that the legacy test method is worst-case, as summarized in reliability report MDT1897325. The EO results in the Table 145 using the old test method passed the ISO 10993-7:2008/AC:2009 acceptance criteria. Therefore, model 10642/8201 is compliant to ISO 10993-7:2008/AC:2009.

9.5 Sterilization Parameters

Table 146 lists the sterilization parameters that were followed for product tested within this report as per the 091033-050 (ref. section 4.0) manufacturing process or equivalent 30-minute sterilization manufacturing processes. All routine sterilization parameters listed in Table 146 were met for product tested within this report. All sterile lot numbers and Sterilization Automated Release System (StARS) reports (containing passing parameter results) are recorded on applicable 'Test Requests' (TR #'s). The TR #'s for each applicable product are referenced in Attachments 1 - 94.

Table 146: Sterilization Parameters

CONDITIONING	
PRESSURE LEAK CHECK BEGINNING	14.0 - 20.0 kPa
TIME	30 - 35 Minutes
#HUMIDITY PULSES	4
TEMPERATURE: CHAMBER	45 - 55°C
CHAMBER LOAD	45 - 55°C
RELATIVE HUMIDITY	55 - 85% RH
PRESSURE, JUST PRIOR TO GAS INJECTION	8 - 14 kPa
FAN TRACES	0.03 Amps - 0.3 Amps
ETO EXPOSURE	
GAS INLET TEMPERATURE	15°C - 75°C
EXPOSURE TIME	27 – 33 Minutes
TEMPERATURE: CHAMBER	45°C - 55°C
CHAMBER LOAD	45°C - 55°C
RELATIVE HUMIDITY	55% - 85% RH
PRESSURE	55 - 75 kPa
GAS CONCENTRATION	≥ 720 mg/l **Note:** Loading configuration name designations vary for each manufacturing facility.
NET GAS CARTRIDGE WEIGHT	122 - 132 grams
FAN TRACES	0.03 Amps - 0.30 Amps
POST VACUUM	
PRESSURE-LOWEST BEFORE AIR FLUSH	20.0 -30.0 kPa
AIR FLUSH	
TIME	25 Minutes Minimum
AERATION	
***TEMPERATURE**	44°-56°C
***FANS**	0.03 - 0.30 Amps

*__NOTE__: If aeration is performed in the sterilizer, the chamber load temperature, chamber temperature and fans must meet aeration parameters.

10.0 DEVIATIONS:

10.1 In protocol BSH111461PC (ref. section 4.0) under Table 18 “CRHF Non-Implantable Accessories” the 6054 stylet model was inadvertently listed as phased out. The 6054 is not phased out. The model was assessed for “CRHF Non-Implantable Accessories” and added to Table 20 within this report. The 6054 was found not to be a worst case model.

10.2 In protocol BSH111461PC (ref. section 4.0) under Table 4 “Pacing Lead Models Based on 2-16 hours aeration at 1X sterilization” the “ICL08B” and “ICL08JB” models were inadvertently not assessed. Therefore, the “ICL08B” and “ICL08JB” models were assessed for “Pacing Lead Models Based on 2-16 hours aeration at 1X sterilization” and were added to Table 4 within this report. The “ICL08B” and “ICL08JB” models were found not to be worst case models.

10.3 In protocol BSH111461PC (ref. section 4.0) under Table 16 “CRHF Small Accessory Implants Based at 1X Sterilization” model “Multi” was inadvertently not assessed. Therefore, the “Multi” model was assessed for “Pacing

Lead Models Based on 2-16 hours aeration at 1X sterilization" and was added to Table 4 within this report. The "Multi" model was found not to be a worst case product.

10.4 Table 16 of protocol BSH111461PC (ref. section 4.0) indicates that the 6717 model contains only 1 pin plug. The 6717 actually contains 2 pin plugs. Therefore, the 6717 with 2 pin plugs was tested.

10.5 Table 48 of protocol BSH111461PC (ref. section 4.0) listed models 6093, 6986M-39, 6295, 6056 and 6052 as needing TCL testing. These models did not need TCL testing since they are all limited contact components. The TCL is calculated from the EO/ECH limited use results. Therefore, these models were only tested for EO/ECH.

10.6 Table 50 of protocol BSH111461PC (ref. section 4.0) indicated simulated extraction (limited contact) testing for the adhesive of model 6986M. The adhesive is a permanent contact component. Therefore, the adhesive was tested through exhaustive extraction rather than simulated extraction.

10.7 Section 8.2.2 of protocol BSH111461PC (ref. section 4.0) instructed to perform simulated extraction at 37°C. However, parts that do not come into contact are to be tested at 25°C. Therefore, simulated extraction temperature was updated for affected components. The following components were extracted at 25°C (dependent upon model type): cap tube, slitters, stylet guide, steering handle, acute retention clip, backloading tool, pinch-on-tool, hex wrenches, guidewire clips, clip-2 and rotation tool. The following was extracted at 37°C (dependent upon model type): veinlifter, stylets and all permanent contact components/leads.

However, the guidewire clip for models 4193-103 and 4194-103 and the stylet guide for the "Blank" control for the 6052 models were inadvertently extracted at 37°C rather than at 25°C. This deviation is acceptable because extraction at a higher temperature will remove EO/ECH residue at a greater rate resulting in a higher residual level result.

10.8 Table 47 of protocol BSH111461PC (ref. section 4.0) listed model 5038-65 (DELP tray) as only needing 3X and 4X sterilization for EO/ECH and TCL analysis. However, 1X data for the 5038-65 qualified within the standard lead tray could only be found. Therefore, EO/ECH and TCL analysis needed to be performed on 1X samples in addition to the 3X and 4X 5038-65 samples within the DELP trays. The 5038-65 sample contained within the standard lead trays was still tested at 3X and 4X as per protocol BSH111461PC (ref. section 4.0).

10.9 Table 12 of protocol BSH111461PC (ref. section 4.0) stated that model 6937A was previously qualified and meets ISO 10993-7. However, this was based off of the -65 length model. The 6937A contains a 100 cm length model. Therefore, it was determined that residual testing needed to be performed since there is no previous data for the 100 cm length. Table 14 of this report was updated to mention that testing was performed.

10.10 Table 4 of protocol BSH111461PC (ref. section 4.0) stated that model 4076 was previously qualified and meets ISO 10993-7. However, this was based off of the -58 length model. The 4076 contains a 110 cm length model. Therefore, it was determined that residual testing needed to be performed since there is no previous data for the 110 cm length. Table 4 of this report was updated to mention that testing was performed.

10.11 Table 6 of protocol BSH111461PC (ref. section 4.0) stated that model 4195 was not a worst case model. However, it was determined that this model contained the longest length (103 cm) in its grouping in Table 8 of this report. Therefore, it was determined that residual testing needed to be performed since there is no previous data for the 103 cm length. Table 8 of this report was updated to mention that testing was performed.

10.12 Table 50 of protocol BSH111461PC (ref. section 4.0) inadvertently listed Clip-2 (part # 119478001) of model 6052 to be tested for EO/ECH residual. The Clip-2 component does not come into human contact. The part is used to hold the stylet tubing in place within the packaging. Therefore, the part was not tested.

10.13 Table 33 of protocol BSH111461PC (ref. section 4.0) inadvertently listed model 6052 as containing a "pinch on tool" part # 800471001. This part does not exist as a component within the 6052 packaging configuration. Therefore, the component was not tested.

10.14 Section 8.2 of protocol BSH111461PC (ref. section 4.0) specifies that five samples for each model/test shall be utilized. Typically, five (5) samples are generally used to reduce statistical error. However, per Section 6.3 of CSS-0911-XXXX-0002 (ref. section 4.0), sample size may vary with written justification. Only three (3) sterilant residual

test samples were processed for 1X, 3X and 4X sterilization of the 6947, 6721L, 4195, and 4076 models and 1X, 2X and 3X for the 6937A model due to high cost and time required for manufacturing.

10.15 Table 13 of protocol BSH111461PC (ref. section 4.0) did not include model 6996ST as being phased out. This model is no longer manufactured and is phased out.

10.16 Section 3.0 of protocol BSH111461PC (ref. section 4.0) did not contain "Length" as part of the Criteria Breakdown determination for worst case models. This criterion was added into the report in section 3.0 as part of the criteria determination to determine worst case leads, extenders and adapters since the longer a lead the potential for higher EO/ECH residual exists. Additional models were identified as worst-case models and were tested. Additional models tested that were not listed in protocol BSH111461PC (ref. section 4.0) are as follows: 6947-100, 4195-103 and 4076-110 (reference section 3.0).

10.17 In protocol BSH111461PC (ref. section 4.0) under Table 9 "Phased-Out Pacing Lead Models Not Assessed" models IHP09JB and ICF09 were inadvertently listed as phased out. The IHP09JB and ICF09 models are not phased out. Both models were assessed for "Pacing Lead Models (Composed of Polyurethane/Silicone and Silicone) Based on a Minimum of 2 Hours Aeration at 1X Sterilization" and added to Table 4 within this report. The IHP09JB and ICF09 models were found not to be worst case models and were not tested.

The deviations listed above have no impact for compliance to ISO 10993-7 (ref. section 4.0).

11.0 CONCLUSION:

The testing results documented in this report demonstrate that all Medtronic CRHF Therapy Delivery System (TDS) internally manufactured and sterilized leads, accessory and adaptor products listed in Table 147 comply with the residual and TCL requirements stated in ISO 10993-7: 2008/AC:2009 (ref. section 4.0) after applying the 30-minute EO sterilization (ref. 091033-050, section 4.0) process of selected worst case models from within each of the four separate groups that were chosen as per BSH111461PC (ref. section 4.0) in the 3M™ 100% ethylene oxide (EO) 5XLe tabletop sterilizer system. There are no changes to the equivalent existing sterilization processes at the CRHF facilities that utilize the 3M™ 100% ethylene oxide (EO) 5XLe tabletop sterilizer system for sterilization of Medtronic product.

Table 147: CRHF Internally Sterilized Leads, Adaptors and Accessories Qualified for 1X-3X Sterilization and Aeration

Model	*Aeration (Hours) after 1X*	*Aeration (Hours) after 2X*	*Aeration (Hours) after 3X*
Multi	*4-16*	*8-16*	*N/A*
080118	*4-16*	*8-16*	*N/A*
2872	*4-16*	*8-16*	*N/A*
3830	*4-16*	*8-16*	*8-16*
Vitatron ICL08	*2-16*	*8-16*	*8-16*
Vitatron IHP09	*4-16*	*8-16*	*8-16*
Vitatron IHP09B	*4-16*	*8-16*	*8-16*
4073/Vitatron ICM09	*2-16*	*8-16*	*8-16*
4074/NPX102/Vitatron ICM09B	*2-16*	*8-16*	*8-16*
*4076/Vitatron ICQ09B	*2-16*	*8-16*	*8-16*
4084	*2-16*	*8-16*	*8-16*
4084MRI	*2-16*	*8-16*	*8-16*
4092/Vitatron IMK49B	*2-16*	*8-16*	*8-16*
4189	*4-16*	*8-16*	*8-16*
4191	*4-16*	*8-16*	*N/A*
4193	*4-16*	*8-16*	*N/A*
4194	*4-16*	*8-16*	*N/A*
4195	*8-16*	*8-16*	*8-16*
4196	*2-16*	*8-16*	*8-16*
4296	*8-16*	*8-16*	*8-16*
4396	*2-16*	*8-16*	*8-16*
4574/NPX103/Vitatron ICM09JB	*2-16*	*8-16*	*8-16*
4584MRI	*2-16*	*8-16*	*8-16*
4592/Vitatron IMK49JB	*2-16*	*8-16*	*8-16*
4965	*4-16*	*8-16*	*8-16*
4968	*4-16*	*8-16*	*8-16*
5033	*2-16*	*8-16*	*8-16*
5038/Vitatron IMW18Q, IMW17Q, IMW16Q, IMW15Q, IMW14Q	*4-16*	*8-16*	*8-16*
5038L	*4-16*	*8-16*	*8-16*
5038S	*4-16*	*8-16*	*8-16*
5054	*2-16*	*8-16*	*8-16*
5071	*2-16*	*8-16*	*8-16*
5072	*2-16*	*8-16*	*8-16*
5076/NPX101/Vitatron ICF09B	*2-16*	*8-16*	*8-16*
5086MRI	*2-16*	*8-16*	*8-16*
5092	*2-16*	*8-16*	*8-16*
5554	*2-16*	*8-16*	*8-16*
5568	*2-16*	*8-16*	*8-16*
5592	*2-16*	*8-16*	*8-16*
5594	*2-16*	*8-16*	*8-16*
5803A	*4-16*	*8-16*	*N/A*
5866-9M	*4-16*	*8-16*	*N/A*

Note: For any testing conducted, minimum aeration was performed.

Table 147: Continued

Model	Aeration (Hours) after 1X	Aeration (Hours) after 2X	Aeration (Hours) after 3X
5866-22	*4-16*	*8-16*	*N/A*
5866-21	*4-16*	*8-16*	*N/A*
5866-23	*4-16*	*8-16*	*N/A*
5866-24M	*4-16*	*8-16*	*N/A*
5866-36	*4-16*	*8-16*	*N/A*
5866-37M	*4-16*	*8-16*	*N/A*
5866-38M	*4-16*	*8-16*	*N/A*
5866-40M	*4-16*	*8-16*	*N/A*
5866-45	*48-50*	*48-50*	*N/A*
5866-46	*48-50*	*48-50*	*N/A*
5867AS	*4-16*	*8-16*	*N/A*
5867-3M	*4-16*	*8-16*	*N/A*
5867-2	*4-16*	*8-16*	*N/A*
5867-5	*4-16*	*8-16*	*N/A*
5873C	*4-16*	*8-16*	*N/A*
5873W	*4-16*	*8-16*	*N/A*
6043	*4-16*	*8-16*	*N/A*
6048	*4-16*	*8-16*	*N/A*
6049	*4-16*	*8-16*	*N/A*
6052	*4-16*	*8-16*	*N/A*
6054	*4-16*	*8-16*	*N/A*
6056	*4-16*	*8-16*	*N/A*
6056M	*4-16*	*8-16*	*N/A*
6057	*4-16*	*8-16*	*N/A*
6081	*4-16*	*8-16*	*N/A*
6082	*4-16*	*8-16*	*N/A*
6091	*4-16*	*8-16*	*N/A*
6093	*4-16*	*8-16*	*N/A*
6094	*4-16*	*8-16*	*N/A*
6228SLT	*4-16*	*8-16*	*N/A*
6254	*4-16*	*8-16*	*N/A*
6282	*4-16*	*8-16*	*N/A*
6293	*4-16*	*8-16*	*N/A*
6295	*4-16*	*8-16*	*N/A*
6701	*4-16*	*8-16*	*8-16*
6707	*4-16*	*8-16*	*8-16*
6717	*4-16*	*8-16*	*8-16*
6718	*4-16*	*8-16*	*8-16*
6719	*4-16*	*8-16*	*8-16*
6721(S, M, L)	*4-16*	*8-16*	*8-16*
6725	*4-16*	*8-16*	*8-16*
6726	*4-16*	*8-16*	*8-16*
6920	*4-16*	*8-16*	*8-16*

Table 147: Continued

Model	*Aeration (Hours) after 1X*	*Aeration (Hours) after 2X*	*Aeration (Hours) after 3X*
6925	*4-16*	*8-16*	*8-16*
6933	*4-16*	*8-16*	*8-16*
6935/NDX101	*8-16*	*8-16*	*8-16*
6935M	*8-16*	*8-16*	*8-16*
6937	*4-16*	*8-16 (2X only for MPROC)*	*8-16*
6937A	*12-16*	*14-16*	*N/A*
6944	*8-16*	*8-16*	*8-16*
6944A	*8-16*	*10-16*	*10-16*
6946M	*8-16*	*8-16*	*8-16*
6947 / NDX102	*8-16*	*8-16*	*8-16*
6947M / NDX402	*8-16*	*8-16*	*8-16*
6981M	*4-16*	*8-16*	*N/A*
6984M	*4-16*	*8-16*	*N/A*
6985M	*4-16*	*8-16*	*N/A*
6986M	*4-16*	*8-16*	*N/A*
6996SQ	*4-16*	*8-16*	*N/A*
7927	*2-16*	*2-16*	*2-16*
Torque Clip	*4-16*	*N/A*	*N/A*

Note: For any testing conducted, minimum aeration was performed.

12.0 ATTACHMENTS:

Attachment Number	Number of Pages	Title
1	1	Summary of 1X EO/ECH Residue Test Results for Permanent Contact for the 7927 Lead
2	1	Summary of 1X TCL Residue Test Results for Permanent Contact for the 7927 Lead
3	1	Summary of 3X EO/ECH Residue Test Results for Permanent Contact for the 7927 Lead
4	1	Summary of 3X TCL Residue Test Results for Permanent Contact for the 7927 Lead
5	1	Summary of 4X EO/ECH Residue Test Results for Permanent Contact for the 7927 Lead
6	1	Summary of 4X TCL Residue Test Results for Permanent Contact for the 7927 Lead
7	4	Summary of 1X EO/ECH Residue Test Results for the 6996SQ-85 Lead
8	1	Summary of 1X TCL Residue Test Results the 6996SQ-85 Lead
9	2	Summary of 3X EO/ECH Residue Test Results for the 6996SQ-85 Lead
10	1	Summary of 3X TCL Residue Test Results for the 6996SQ-85 Lead

11	2	Summary of 4X EO/ECH Residue Test Results for the 6996SQ-85 Lead
12	1	Summary of 4X TCL Residue Test Results for the 6996SQ-85 Lead
13	4	Summary of 1X EO/ECH Residue Test Results for the 5568-53 Lead – Standard Lead Tray
14	1	Summary of 1X TCL Residue Test Results for the 5568-53 Lead – Standard Lead Tray
15	2	Summary of 3X EO/ECH Residue Test Results for the 5568-53 Lead – Standard Lead Tray
16	1	Summary of 3X TCL Residue Test Results for the 5568-53 Lead – Standard Lead Tray
17	2	Summary of 4X EO/ECH Residue Test Results for the 5568-53 Lead – Standard Lead Tray
18	1	Summary of 4X TCL Residue Test Results for the 5568-53 Lead – Standard Lead Tray
19	4	Summary of 1X EO/ECH Residue Test Results for the 5568-53 Lead – DELP Tray
20	1	Summary of 1X TCL Residue Test Results for the 5568-53 Lead – DELP Tray
21	2	Summary of 3X EO/ECH Residue Test Results for the 5568-53 Lead – DELP Tray
22	1	Summary of 3X TCL Residue Test Results for the 5568-53 Lead – DELP Tray
23	2	Summary of 4X EO/ECH Residue Test Results for the 5568-53 Lead – DELP Tray
24	1	Summary of 4X TCL Residue Test Results for the 5568-53 Lead – DELP Tray
25	4	Summary of 3X EO/ECH Residue Test Results for the 5038-65 Lead – Standard Lead Tray
26	1	Summary of 3X TCL Residue Test Results for the 5038-65 Lead – Standard Lead Tray
27	2	Summary of 4X EO/ECH Residue Test Results for the 5038-65 Lead – Standard Lead Tray
28	1	Summary of 4X TCL Residue Test Results for the 5038-65 Lead – Standard Lead Tray
29	4	Summary of 1X EO/ECH Residue Test Results for the 5038-65 Lead – DELP Tray

30	1	Summary of 1X TCL Residue Test Results for the 5038-65 Lead – DELP Tray
31	2	Summary of 3X EO/ECH Residue Test Results for the 5038-65 Lead – DELP Tray
32	1	Summary of 3X TCL Residue Test Results for the 5038-65 Lead – DELP Tray
33	2	Summary of 4X EO/ECH Residue Test Results for the 5038-65 Lead – DELP Tray
34	1	Summary of 4X TCL Residue Test Results for the 5038-65 Lead – DELP Tray
35	4	Summary of 3X EO/ECH Residue Test Results for the 4193-103 Lead – DELP Tray
36	1	Summary of 3X TCL Residue Test Results for the 4193-103 Lead – DELP Tray
37	4	Summary of 3X EO/ECH Residue Test Results for the 4194-103 Lead – DELP Tray
38	1	Summary of 3X TCL Residue Test Results for the 4194-103 Lead – DELP Tray
39	4	Summary of 1X EO/ECH Residue Test Results for the 4073-65 Lead – DELP Tray
40	1	Summary of 1X TCL Residue Test Results for the 4073-65 Lead – DELP Tray
41	2	Summary of 3X EO/ECH Residue Test Results for the 4073-65 Lead – DELP Tray
42	1	Summary of 3X TCL Residue Test Results for the 4073-65 Lead – DELP Tray
43	2	Summary of 4X EO/ECH Residue Test Results for the 4073-65 Lead – DELP Tray
44	1	Summary of 4X TCL Residue Test Results for Permanent Contact for the 4073-65 Lead – DELP Tray
45	2	Summary of 1X EO/ECH Residue Test Results for the 6717 Accessory Model – Accessory Tray
46	1	Summary of 1X TCL Residue Test Results for the 6717 Accessory Model – Accessory Tray
47	1	Summary of 3X EO/ECH Residue Test Results for the 6717 Accessory Model – Accessory Tray
48	1	Summary of 3X TCL Residue Test Results for the 6717 Accessory Model – Accessory Tray

49	1	Summary of 4X EO/ECH Residue Test Results for the 6717 Accessory Model – Accessory Tray
50	1	Summary of 4X TCL Residue Test Results for the 6717 Accessory Model – Accessory Tray
51	2	Summary of 1X EO/ECH Residue Test Results for the 6295 Accessory Model – Accessory Tray
52	1	Summary of 3X EO/ECH Residue Test Results for the 6295 Accessory Model – Accessory Tray
53	4	Summary of 1X EO/ECH Residue Test Results for the 6986M-39 Accessory Model – Standard Lead Tray
54	2	Summary of 1X TCL Residue Test Results for the 6986M-39 Accessory Model – Standard Lead Tray
55	2	Summary of 3X EO/ECH Residue Test Results for the 6986M-39 Accessory Model – Standard Lead Tray
56	2	Summary of 3X TCL Residue Test Results for the 6986M-39 Accessory Model – Standard Lead Tray
57	4	Summary of 1X EO/ECH Residue Test Results for the 6093 Accessory Model – Stylet Pouch
58	2	Summary of 3X EO/ECH Residue Test Results for the 6093 Accessory Model – Stylet Pouch
59	2	Summary of 1X EO/ECH Residue Test Results for the 6056 Accessory Model – Accessory Tray
60	1	Summary of 3X EO/ECH Residue Test Results for the 6056 Accessory Model – Accessory Tray
61	3	Summary of 1X EO/ECH Residue Test Results for the 6052 Stylet Model – Stylet Pouch
62	2	Summary of 3X EO/ECH Residue Test Results for the 6052 Stylet Model – Stylet Pouch
63	3	Summary of 1X EO/ECH Residue Test Results for the 6052 Stylet Model – Standard Lead Tray
64	2	Summary of 3X EO/ECH Residue Test Results for the 6052 Stylet Model – Standard Lead Tray
65	2	Summary of 1X EO/ECH Residue Test Results for the 6721L Patch – Stylet Pouch
66	1	Summary of 1X TCL Residue Test Results for the 6721L Patch – Stylet Pouch
67	1	Summary of 3X EO/ECH Residue Test Results for the 6721L Patch – Stylet Pouch

68	1	Summary of 3X TCL Residue Test Results for the 6721L Patch – Stylet Pouch
69	1	Summary of 4X EO/ECH Residue Test Results for the 6721L Patch – Stylet Pouch
70	1	Summary of 4X TCL Residue Test Results for the 6721L Patch – Stylet Pouch
71	4	Summary of 1X EO/ECH Residue Test Results for the 6937A-100 Lead Model – Standard Lead Tray
72	1	Summary of 1X TCL Residue Test Results for the 6937A-100 Lead Model – Standard Lead Tray
73	2	Summary of 2X EO/ECH Residue Test Results for the 6937A-100 Lead Model – Standard Lead Tray
74	1	Summary of 2X TCL Residue Test Results for the 6937A-100 Lead Model – Standard Lead Tray
75	2	Summary of 3X EO/ECH Residue Test Results for the 6937A-100 Lead Model – Standard Lead Tray
76	1	Summary of 3X TCL Residue Test Results for the 6937A-100 Lead Model – Standard Lead Tray
77	2	Summary of 1X EO/ECH Residue Test Results for the 6947-100 Lead – Standard Lead Tray
78	1	Summary of 1X TCL Residue Test Results for the 6947-100 Lead – Standard Lead Tray
79	1	Summary of 3X EO/ECH Residue Test Results for the 6947-100 Lead – Standard Lead Tray
80	1	Summary of 3X TCL Residue Test Results for the 6947-100 Lead – Standard Lead Tray
81	1	Summary of 4X EO/ECH Residue Test Results for the 6947-100 Lead – Standard Lead Tray
82	1	Summary of 4X TCL Residue Test Results for the 6947-100 Lead – Standard Lead Tray
83	2	Summary of 1X EO/ECH Residue Test Results for the 4076-110 Lead – DELP Tray
84	1	Summary of 1X TCL Residue Test Results for the 4076-110 Lead – DELP Tray
85	1	Summary of 3X EO/ECH Residue Test Results for the 4076-110 Lead – DELP Tray
86	1	Summary of 3X TCL Residue Test Results for the 4076-110 Lead – DELP Tray

87	1	Summary of 4X EO/ECH Residue Test Results for the 4076-110 Lead – DELP Tray
88	1	Summary of 4X TCL Residue Test Results for the 4076-110 Lead – DELP Tray
89	2	Summary of 1X EO/ECH Residue Test Results for the 4195-103 Lead – DELP Tray
90	1	Summary of 1X TCL Residue Test Results for the 4195-103 Lead – DELP Tray
91	1	Summary of 3X EO/ECH Residue Test Results for the 4195-103 Lead – DELP Tray
92	1	Summary of 3X TCL Residue Test Results for the 4195-103 Lead – DELP Tray
93	1	Summary of 4X EO/ECH Residue Test Results for the 4195-103 Lead – DELP Tray
94	1	Summary of 4X TCL Residue Test Results for the 4195-103 Lead – DELP Tray